Instructions for Use
Maxillary Distractor

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

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DePuy Synthes
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Instructions for Use

Please read these instructions for use, the Synthes brochure "Important Information" and the corresponding surgical technique Maxillary Distractor (DSEM/CMF/0516/0129) carefully before use. Ensure that you are familiar with the appropriate surgical technique.

Material(s)

Component(s)	Material(s)	Standard(s)
Screws	316L Stainless Steel	ISO 5832-1
Distractor body	316L Stainless Steel	ISO 5832-1
Footplates	316L Stainless Steel	ISO 5832-1

Intended use

The Maxillary Distractor is intended for use as a bone stabilizer and lengthening device, where gradual bone distraction is required.

Indications

The Maxillary Distractor is indicated for use in craniofacial surgery, reconstructive procedures, and selective orthognathic surgery of the maxilla. Specifically, it is intended for distraction of the maxilla utilizing a LeFort I osteotomy in adult and pediatric populations.

Contraindications

The Maxillary Distractor is contraindicated in patients previously sensitized to nickel.

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, 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.

Device Specific Adverse Effects

Choking hazard:
– Choking hazard due to the silicone tip guard used to protect the end of the activation hex coming unfastened due to rubbing.

Re-operation:
1. Re-operation due to relapse.
2. Re-operation because the distractor system breaks or disengages due to patient excessive activities.
3. Re-operation because the footplate breaks after implantation surgery, during treatment due to decreased strength as a result of excessive bending of the footplate during implantation.
4. Re-operation because the footplate breaks postoperatively prior to bone consolidation process is completed due to an excessive strain by the patient.
5. Non-union or fibrous union leading to re-operation (worst case) because the number of screws used with the footplates is not sufficient.
6. Re-operation due to the screw migration in thin bone.
7. Premature bone consolidation requiring reoperation due to the distractor being activated in the wrong direction after being activated in the proper direction.
8. Re-operation 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.
9. Re-operation to replace the device due to device disturbance by traumatic patient injury not related to procedure or treatment.
10. Restricted/impaired bone growth requiring further surgery because the distractor is not removed after healing is accomplished.
11. Re-operation due to infection at the distractor site.
12. Re-operation due to device malfunction.
13. Re-operation due to inadequate device length selected.
14. Re-operation due to device backup.
15. Re-operation due to loose distractor footplate.
16. Re-operation due to bone fracture under load.
17. Re-operation due to incomplete osteotomies.

Additional medical treatment for:
18. Soft tissue erosion due to the distractor components pressure on the soft tissue.
19. Patient pain due to end of distractor protruding into soft tissue.
20. Nerve damage requiring subsequent medical treatment.
21. Infection requiring treatment.
22. Injury of the patient due to extended OR time, because the screws/distractors can not be removed.
23. The healing process may be altered for patients with certain metabolic diseases, with active infection or who are immune compromised.
24. Cellulitis.
25. Discomfort of the patient due to long treatment duration.
26. Scar requiring revision.
27. Pain at bony generate site.
28. Wound dehiscence.
29. Treatment termination due to the patient incompliance.
30. Mild anterior open bite.
31. 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.

These devices are intended for single use only and are offered non-sterile or sterile-packed.

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

Preoperative Planning Precautions:
Do not activate the distractors during model surgery, as the distractors are designed for a single activation cycle only. Activation beyond one cycle could cause the distractors to bind.

When placing the distractors consider and verify:
– Occlusal plane
– Tooth buds and roots
– Planned vector of distraction
– Planned length of advancement (consider relapse and overcorrection)
– Adequate bone quality for screw placement.
– Location of nerves
– Lip closure
– Soft tissue coverage
– Patient pain due to distractor interference with soft tissue
– Access to the screws based on approach

Cut and Contour of Footplates:
- Footplates should be cut so that the integrity of the screw hole is not compromised.
- At least three screws must be used in each footplate to ensure adequate stability.
- Cut the implant immediately adjacent to the screw holes.
- Take care to protect soft tissue from trimmed edges.

Mark Distractor Location:
- 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.
- Firmly press the screwdriver blade into the screw recess to ensure retention of the screw on the screwdriver blade.
- Take care to avoid nerves, tooth buds and roots and other critical structures when drilling and/or placing screws.
- Use the appropriate screw length to avoid distractor loosening or damage of critical/lingual structures.
- The screws should not be fully tightened, as they will be removed prior to performing the osteotomy.
- Use the drill bit size assigned for the system screw.
- Screws can loosen during the course of treatment if placed in poor quality bone.
- Take care while drilling as to not damage, entrap, or tear a patient's soft tissue or damage critical structures. Be sure to keep drill clear of loose surgical materials.
- Handle devices with care and dispose worn bone cutting instruments in an approved sharps container.

Reattachment of Distractor:
- Take care to avoid nerves, tooth buds and roots and/or other critical structures when drilling and/or placing screws.
- Use the drill bit size assigned for the system screw
- Screws can loosen during the course of treatment if placed in poor quality bone.
- 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.
- 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 or lingual structures.
- A minimum of three screws must be used in each footplate to ensure adequate stability.
- Avoid nerves, tooth buds, roots or other critical structures when drilling and/or placing screws. One or both of the holes (A) and (B) on the anterior footplate must contain a screw.
- Handle devices with care and dispose worn bone cutting instruments in an approved sharps container.

Complete Osteotomy:
- 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.
- Take care to avoid nerves.

Postoperative Considerations:
- 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.
- A rate of 1.0 mm of distraction per day is recommended to prevent premature consolidation.
- 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, and contact their surgeon immediately if they loose the activation instrument.

Device Removal:
- To avoid implant migration the distractor should be removed after treatment.

Instrument Precaution:
- Dispose worn bone cutting instruments in an approved sharps container.

Warnings
- Excessive and reverse bending or the use of incorrect instrumentation for bending may weaken the footplate and lead to premature footplate failure (e.g. breakage).
- Do not bend the footplate beyond what is required to match the anatomy.
- The alignment rods should not be used as leverage for bending the footplates as this may cause damage to the distractor bodies.
- 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.
- Instruments and screws may have sharp edges or moving joints that may pinch or tear user's glove or skin.
- Medical devices containing stainless steel may elicit an allergic reaction in patients with hypersensitivity to nickel.
- If the silicone tip guard is used to protect the activation end of the distractor body, it presents a choking hazard, if it becomes lose and it disengages from the activation end.

General Information
- The manufacturer is not responsible for any complications arising from incorrect diagnosis, choice of incorrect implant, incorrectly combined implant components and/or operating techniques, the limitations of treatment methods, or inadequate asepsis.
- The implant components applied (name, article number, lot number) must be documented in each patient's record.

Combination of medical devices
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 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 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.

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

PLANNING
1. Determine the post-distraction anatomic goal by conducting an evaluation of the craniofacial pathology, the bone quality and asymmetry through clinical exam, CT scan, cephalogram and/or panoramic x-ray.
2. Select the appropriate distractor size based on patient age and anatomy.
3. Correct placement and orientation of osteotomies and distraction devices is critical to successful treatment.

PLACING DISTRACTORS
1. Make the incision. Elevate the periosteum to expose the bone.
2. Mark the approximate site of the osteotomy and distractor placement on the bone.
3. Fit the distractor. Place the distractor in the intended area to assess the patient's anatomy and determine the approximate location of the footplates, bone screws.
4. If the distractor was not cut and contoured preoperatively, the distractor must be fitted to the bone.
5. Cut and contour footplates. Cut the footplates using the cutter to remove any unnecessary screw holes. Cut the footplates so the cut edges are flush with the distractor. Cut the implant immediately adjacent to the screw holes. Contour the footplates to the bone using the bending pliers.
6. Before making the osteotomy, mark the position of the distractor by drilling and/or inserting one appropriate size and length screw through each footplate. Do not fully tighten the screws. Screws should not be fully tightened as they will be removed prior to performing the osteotomy.
7. Unscrew and remove the distractor. Perform the osteotomy.
8. Reattach the distractor by aligning the footplates with the holes made previously. Drill and/or insert the remaining appropriate size and length screws. Fully tighten all screws.
9. Confirm device stability and verify movement of the bone. Use the activation instrument to engage the hexagonal activation tip of the distractor. Rotate in the direction marked on the instrument handle, to confirm device stability and verify movement of the bone. Return the distractor to its original position.
10. Repeat steps for bilateral procedures. Close all incisions.

LATENCY PERIOD
Begin active distraction three to five days after device placement. For young patients, active distraction can begin earlier, to prevent premature consolidation.

ACTIVATION PERIOD
1. Document progress. Distraction progress should be observed by documenting the changes in the patient's anterior maxillary and mandibular occlusion. A Patient Care Guide, DSEM/CMF/0516/0130, is included with the system to help record and monitor device activation.
2. 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.

CONSOLIDATION PERIOD
After the desired advancement has been achieved, the new bone must be given time to consolidate, the duration of which is at least six to eight weeks. This time period may vary in relation to patient age and should be determined by clinical evaluation.

DISTRACTOR REMOVAL
After the consolidation period, remove the distractors by exposing the anterior and posterior footplates through the same maxillary vestibular incision, and removing the bone screws.

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, DSEM/CMF/0516/0130, 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. 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 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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