Instructions for Use
Internal Midface Distractor

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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 Internal Midface Distractor, DSEM/CMF/0516/0131, carefully before use. Ensure that you are familiar with the appropriate surgical technique.

Distraction Systems:
Internal Midface Distractor

Internal Midface Distractor

Component(s)	Material(s)	Standard(s)
Screws	TAN	ISO 5832-11
Distractor body	TAN	ISO 5832-11
Footplates	TAN	ISO 5832-11

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

Indications
The Internal Midface Distractor is indicated for reconstructive osteotomies and segment advancement of cranial and midface bones for correction of conditions such as of as syndromic craniosynostosis and midface retrusion in adult and pediatric populations.

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, 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 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 offered Sterile and Non-sterile. These devices are intended for single use only.

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:
When placing the distractors consider and verify:
- Planned length of advancement (consider relapse and overcorrection)
- Adequate bone quality for screw placement.
- Location of nerves
- Soft tissue coverage
- Patient pain due to distractor interference with soft tissue
- Access to the screws based on approach

Distractor Assembly:
Screws must be placed in the holes closest to the footplate for adequate device stability.

Cut and Contour of Footplates:
- Footplates should be cut so that the integrity of the screw hole is not compromised.
- Cut the implant immediately adjacent to the screw holes.
- Take care to protect soft tissue from trimmed edges.
- Each footplate should contain a minimum of four screws for adequate stability.

Attachment of Extension Arm:
- Determine if the activation arm extension(s) are necessary for the activation hex to exit through the soft tissue for activation.
- Choose an adequate length extension arm to ensure that the soft tissue does not obstruct the activation hex during distraction.
- Extension arm should be assembled with the distractor before the distractor is attached to the bone. It is difficult to attach the extension arm after the distractor is screwed to the bone.
- During the course of treatment, care should be taken to protect the extension arms and prevent damage or breakage. Lateral forces from a patient rolling on the flexible extension arms during sleep can damage and/or break the extension arms. It is advised to secure the flexible arms to the patient's skin, without affecting the arm's ability to rotate. As an alternative, rigid extension arms are available.

Marking for Distractor Location:
- Use the drill bit size assigned for the system screw.
- Drill and insert screws closest to the osteotomy first.
- Do not fully tighten screw in the posterior footplate.
- 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.
- Take care while drilling as to not damage, entrap, or tear a patient's soft tissue or damage critical structures.
- Bone screws should be placed in areas of hard cortical bone to provide stable fixation. Screws can loosen during the course of treatment if placed in poor quality bone.
- Activate the distractor in open direction a half turn prior to drilling and/or inserting screws to ensure adequate distance between the pilot holes and the osteotomy.
- 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.
- 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.

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.

Reattachment of Distractor:
- To increase distractor stability in thin bone, insert screws bicortically. In addition, more screws can be used.
- 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 and insert screws closest to the osteotomy first.

– 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.
– Take care while drilling as to not damage, entrap, or tear a patient's soft tissue or damage critical structures.
– Bone screws should be placed in areas of hard cortical bone to provide stable fixation.
– 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.
– Firmly press the screwdriver blade into the screw recess to ensure retention of the screw on the screwdriver blade.
– Extension arm should be assembled with the distractor before the distractor is attached to the bone. It is difficult to attach the extension arm after the distractor is screwed to the bone.
– Use the appropriate screw length to avoid distractor loosening or damage of critical or lingual structures.
– Each footplate should contain a minimum of four screws for adequate stability.
– Screws must be placed in the holes closest to the distractor body for adequate device stability.

Confirmation of Device Activation:
– Do not hold the extension arm while rotating it with the activation instrument. Doing so will make it difficult to rotate the extension arm and may cause the extension arm to separate from the distractor.

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.
– Do not hold the extension arm while rotating it with the activation instrument. Doing so will make it difficult to rotate the extension arm and may cause the extension arm to separate from the distractor.
– During the course of treatment, monitor the patient's condyles in the glenoid fossae for degenerative changes.
– The surgeon must instruct the patient/care giver how to activate and protect the distractor during the treatment.
– It is important that the extension arms be protected from catching on objects that could pull the devices and cause the patient pain or injury.
– 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.

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

Instrument Precaution:
– 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.

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

Distractor Implantation:
– Do not implant a distractor if the footplates have been damaged by excessive bending.
– If the 1.2 mm machine screw is not used, extra care should be taken to not reverse the distractor during distraction, as it can inadvertently disengage from the anterior footplate.
– If the 1.2 mm machine screws were not used to lock the anterior footplates to the distractor bodies, ensure the two components are fully engaged when the devices are returned to their original position.
– The devices are capable of 40 mm of distraction (80 counterclockwise rotations). Distraction beyond this limit will cause the devices to separate.

Attachment of extension arm:
– The screwdriver must be used to fully tighten the extension arm to the distractor. If the screwdriver is not used, the extension arm may separate from the distractor unintentionally.

Postoperative Considerations:
– During the course of treatment, care should be taken to protect the extension arms and prevent damage or breakage. Lateral forces from a patient rolling on the flexible extension arms during sleep can damage and/ or break the extension arms. It is advised to secure the flexible arms to the patient's skin, without affecting the arm's ability to rotate. As an alternative, rigid extension arms are available.
– Patients should be advised to avoid high risk activities, as injury can occur if the patient falls on the device.
– The devices are capable of 40 mm of distraction (80 counterclockwise rotations). Distraction beyond this limit will cause the devices to separate.

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 volume, and asymmetry through clinical exam, CT scan, cephalogram and/or panoramic x-ray.
2. 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, and/or extension arm.
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. Attach the extension arms. Select the appropriate length extension arm based on the planned amount of distraction and the desired location of the activation tip of the extension arm.
7. 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.
8. Unscrew and remove the distractor. Perform the osteotomy.
9. 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.
10. Confirm device stability and verify movement of the bone. Use the activation instrument to engage the hexagonal activation tip of the distractor or of the extension arm. 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.
11. 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 occlusion. A Patient Care Guide 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.
3. Do not hold the extension arm while rotating it with the activation instrument. Doing so will make it difficult to rotate the extension arm and may cause the extension arm to separate from the distractor.

CONSOLIDATION PERIOD
1. After the desired advancement has been achieved, the new bone must be given time to consolidate. This time period may vary in relation to patient age and should be determined by clinical evaluation.
2. The extension arms could be removed at the start of the consolidation phase.
3. If the connection between the distractor and extension arm is buried under the soft tissue, it may be difficult to remove the extension arm. If this occurs, the extension arm can remain intact for the duration of the consolidation period.

DISTRACTOR REMOVAL
1. After the consolidation period, remove the distractors by exposing the footplates through the same incisions that were used during the initial placement surgery, and removing the titanium bone screws.
2. The distractors are easier to remove if the extension arms are removed before distractor removal.

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. To avoid the accretion of dried blood to the device, a regimen of applying antibiotic ointment to the percutaneous port is recommended throughout the course of distraction.
8. Upon the first activation, special care should be given to ensure that the activation hex is free from soft tissue adhesion. Similar care should be given on all subsequent activations to provide the most comfort for the patient.
9. Keeping the hair short around the activation port can also be beneficial to the patient's comfort during distraction.
10. Contact your surgeon immediately, if you loose the activation instrument.
11. During the course of treatment, care should be taken to protect the extension arms and prevent damage or breakage. Lateral forces from a patient rolling on the flexible extension arms during sleep can damage and/ or break the extension arms.
12. Protect the extension arms from catching on objects that could pull the devices and cause the patient pain or injury.
13. Keep the wound area clean during treatment.
14. 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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