Instructions for Use
Alveolar Distractor

Please read these instructions for use, the Synthes brochure "Important Information" and the corresponding surgical technique of Alveolar Distractor 036.000.304 carefully before use. Ensure that you are familiar with the appropriate surgical technique.

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DePuy Synthes
COMPANIES OF Johnson&Johnson

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Alveolar Distractor

Material(s)

Material(s):	Standard(s):
Screws TAN	ISO 5832-11:1994
Footplates TiCP	EN ISO 5832-2: 2012
Distractor body TAN	ISO 5832-11:1994

All Instruments:
- Stainless Steel — EN 10088-1&3: 2014
- Aluminum
  Standards:
  ASTM B209M: 2010
  ASTM B221M: 2013
  EN 573-3: 2013
  DIN 17611: 2011
- PTFE — FDA-Compliant

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

Indications
The Alveolar Distraction System is indicated for vertical bone lengthening of the alveolar ridge in the mandible and the maxilla where gradual bone distraction is required, including deficiency in bone height as a result of: trauma, resorption after dental extraction, periodontal disease, tumor resection, congenital deformity.

Contraindications:
The Alveolar Distractor has no contraindication.

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 hyper 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 Events
Device specific adverse events include but are not limited to:
Bone breakage or bone resorption, inflammatory response, neurological complications (eg. sensory disturbance, paresthesia).

Device specific adverse events could result in re-operation or additional medical treatment:
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. Re-operation to remove device due to allergic reaction to device material/biological sensitivity to implant
6. Non-union or fibrous union leading to re-operation (worst case) because the number of screws used with the footplates is not sufficient.
7. Re-operation due to the screw migration in thin bone.
8. Premature bone consolidation requiring reoperation due to the distractor being activated in the wrong direction after being activated in the proper direction.
9. 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.
10. Re-operation to replace the device due to device disturbance by traumatic patient injury not related to procedure or treatment.
11. Restricted/impaired bone growth requiring further surgery because the distractor is not removed after healing is accomplished.
12. Re-operation due to infection at the distractor site
13. Re-operation due to device malfunction
14. Re-operation due to inadequate device length selected
15. Re-operation due to device backup
16. Re-operation due to loose distractor footplate
17. Re-operation due to bone fracture under load
18. Re-operation due to incomplete osteotomies

Additional medical treatment for:
1. Soft tissue erosion due to the distractor components pressure on the soft tissue
2. Patient pain due to end of distractor protruding into soft tissue.
3. Nerve damage requiring subsequent medical treatment.
4. Infection requiring treatment
5. Injury of the patient due to extended OR time, because the screws/distractors can not be removed
6. The healing process may be altered for patients with certain metabolic diseases, with active infection or who are immune compromised.
7. Cellulitis
8. Discomfort of the patient due to long treatment duration
9. Pain at bony generate site
10. Wound dehiscence
11. Treatment termination due to the patient incompliance
12. 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 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.

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.

Be aware that implants are not as strong as native bone. Implants subjected to substantial loads may fail. Medical devices containing stainless steel may elicit an allergic reaction in patients with hypersensitivity to nickel.

Precautions
– When placing and implanting the distractors consider and verify, as appropriate:
A. Interference with occlusion
B. Location of nerves tooth buds and roots and other critical structures when drilling and/or placing screws.
C. Adequate bone volume and quantity for screw placement.
D. Lip closure
E. Soft tissue coverage
F. Patient pain due to distractor interference with soft tissue
G. Patient access of the barrel for proper distraction.

– Perform a temporary pre-activation of the distractor prior to initial placement, which compensates for the bone volume that will be lost by the osteotomy cut. Once the distractor is reattached after the osteotomy, counter-activation permits minimization of the osteotomy gap.
– Use the appropriate screw length to avoid distractor loosening or damage of critical/lingual structures.
– Select a device with sufficient distraction length to allow for the planned distraction.
– Footplates should be cut so that the integrity of the screw hole is not compromised.
– Cut any sharp edges.
– Lock the angulation mechanism after determining the vector by firmly tightening the green fixation screw clockwise.
– Care should be taken to not overtighten the green fixation screw as it may damage the distractor.
– Avoid excessive and reverse bending as it may weaken the plate and lead to premature implant failure.
– Use the drill bit size assigned for the screws used to fix the distractor.
– Use the appropriate screw length to avoid distractor loosening or damage of critical/lingual structures.
– Irrigate during drilling to avoid thermal damage to the bone.
– Drilling speed should never exceed 1800 RPM. Higher speed can result in thermal necrosis of the bone and increased hole diameter and may lead to unstable fixation.
– Drill and insert screws closest to the osteotomy first.
– Do not apply too much force when tightening the screws.
– Irrigate and apply suction for removal of debris potentially generated during implantation.
– After implant placement is complete, discard any fragments or modified parts in an approved sharps container.
– A rate of 1.05 mm of distraction per day (one turn three times a day) is recommended to prevent premature consolidation.

Warnings
– This description alone does not provide sufficient background for direct use of the instrument set.
– Instruction by a surgeon experienced in handling these instruments is highly recommended.
– Pliers should be used to hold the distractor by its footplates only. Holding the distractor barrel with pliers may damage the distractor.

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

MRI Information
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 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).

Precaution
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 thermo regulation 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
The specific operation instructions are described in the distractor Surgical Technique: Alveolar Distractor 036.000.304.

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. 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.
3. Fit the distractor. Place a distractor in the intended area to assess the patient's anatomy and determine the approximate location of the footplates and bone screws.
4. If the distractor was not cut and contoured preoperatively, the device 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.
6. Contour the footplates to the bone using the bending pliers.
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 at this point, to avoid compromising bone integrity.
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. A minimum of two screws should be placed in the base plate for adequate stability during distraction of narrow bone segments. Wider distraction segments may require more screws in the base plate.
11. Confirm device activation. 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.
12. 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.

CONSOLIDATION PERIOD
After the desired advancement has been achieved, the new bone must be given time to consolidate. This time period may vary and should be determined by clinical evaluation.

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 bone screws.
2. For additional screw removal options refer to the Universal Screw Removal Set brochure 036.000.773.

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. Contact your surgeon immediately, if you loose the activation instrument.
7. Keep the wound area clean during treatment.
8. Maintain good oral hygiene during all phases of treatment.

Processing / reprocessing of the device

Detailed instructions for processing implants and reprocessing reusable devices, instrument trays and cases are described in the DePuy Synthes brochure "Important Information". Assembly and disassembly instructions of instruments "Dismantling multipart instruments" can be downloaded from
http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance

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