Instructions for Use
Distraction Systems

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

DePuy Synthes
CMF
COMPANIES OF Johnson&Johnson

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Instructions for Use

Distraction Systems:
Internal Midface Distractor
Craniomaxillofacial (CMF) Distractor
Maxillary Distractor System
Single Vector Distractor
Alveolar Distractor
Multi-Vector Distractor
External Midface Distractor
Universal Screw Removal Set

Please read these instructions for use, the Synthes brochure "Important Information" and the corresponding surgical techniques
Internal Midface Distractor 036.000.919
Craniomaxillofacial (CMF) Distractor 036.000.731
Maxillary Distractor 036.000.4151
Single Vector Distractor 036.000.409 and 036.000.533
Alveolar Distractor 036.000.304
Multi-Vector Distractor 036.000.410
External Midface Distractor 036.000.920
Universal Screw Removal Set 036.000.773
carefully before use. Ensure that you are familiar with the appropriate surgical technique.

Material(s)
Material(s): Standard(s):
INTERNAL MIDFACE DISTRACTOR
Screws TAN, ISO 5832-11
Footplates TAN, ISO 5832-11
Distractor body TAN, ISO 5832-11
Extension arms:
Silicone, ASTM F 2042
L605, ASTM F 90

CRANIOMAXILLOFACIAL DISTRACTOR (CMFD)
Screws TAN, ISO 5832-11
Footplates TiCP, ISO 5832-2
Distractor body TAN, ISO 5832-11 and CoCrTgNi, ISO 5832-5
Extension arms:
Silicone, ASTM F 2042
MP35N, ASTM F 562, ISO 5832-6
L605, ASTM F 90

SINGLE-VECTOR DISTRACTOR (STEEL)
Screws Stainless Steel, ISO 5832-1
Footplates Stainless Steel, ISO 5832-1
Distractor body Stainless Steel, ISO 5832-1

SINGLE-VECTOR DISTRACTOR (TITANIUM)
Screws TiCP, ISO 5832-2
Footplates TAN, ISO 5832-11
Distractor body TAN, ISO 5832-11

MAXILLARY DISTRACTOR
Screws Stainless Steel 316L, ISO 5832-1
Footplates Stainless Steel 316L, ISO 5832-1
Distractor body Stainless Steel 316L, ISO 5832-1

ALVEOLAR DISTRACTOR
Screws TAN, ISO 5832-11
Footplates TiCP, ISO 5832-2
Distractor body TAN, ISO 5832-11

MULIT-VECTOR DISTRACTOR,
Distractor body TAV, ISO 5832-3 /Stainless Steel 304, ISO 7153-1
Distractor Arm TAV, ISO 5832-3 /Stainless Steel 304, ISO 7153-1
Kirschner Wires Stainless Steel
Carbon Fiber Rod CFRE, ISO 16061
Nut Stainless Steel 304, ISO 7153-1
Cap: PVC

EXTERNAL MIDFACE DISTRACTOR
Screws TAN, ISO 5832-11
Footplates TiCP, ISO 5832-2
Frame, TAN, ISO 5832-11 and Al Alloy, DIN EN 573 and Crabon Fiber, ISO 16061 and and PTFE, FDA Compliante USP Cl VI and Stainless Steel, DIN EN 10088-1-3 and TAV, ISO 5832-3 and Stainless Steel,17-4PH, ASTM B 209 and RADEL R5500-BK937, FDA Compliante USP Cl VI
Halo Pins TAN, ISO 5832-11
Connecting Rods TAV, ISO 5832-3
Carbon Fiber Rods CFRE, ISO 16061

All Instruments:
– Stainless Steel, DIN EN 10088-1&3
– Aluminum
Standards:
ASTM B209M
ASTM B221M
DIN EN 573-3
DIN 17611
– PTFE, FDA-Compliant

Intended use
The Internal Midface Distractor, the Maxillary Distractor, the Single Vector Distractor, the Alveolar Distractor, the External Midface Distractor is intended for use as a bone stabilizer and lengthening device, where gradual bone distraction is required. The Craniomaxillofacial (CMF) Distractor and Synthes Multi-Vector Distractor is intended for use as a bone stabilizer and lengthening (and/or transport) device, where gradual bone distraction is required.

Universal Screw Removal Set is intended to be used for the removal of intact and damaged screws. It is not intended to be used in combination with a Power Tool.

Indications
The Internal Midface Distraction System 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.
The Craniomaxillofacial (CMF) Distraction System is indicated for correction of congenital deficiencies or post-traumatic defects of the mandibular body and ramus where gradual bone distraction is required. The system of 1.0 mm and 1.3 mm is recommended for children under the age of 12 months and 1.5 mm and 2.0 mm is recommended for older patients.
The Maxillary Distraction System 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.
The Single Vector Distraction Systems (SST and Ti Mandible Distractor) are indicated for use in mandibular bone lengthening to correct conditions as congenital mandibular deficiencies or posttraumatic defects.
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.
The Multi-Vector Distractor System is indicated for mandibular bone lengthening in conditions such as mandibular hypoplasia or post-traumatic defects of the mandible where gradual bone distraction is required. It is also indicated for mandibular reconstruction after severe trauma or tumor resection bone loss, as an alternative to bone grafts and free flaps.
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 bone distraction is required in adult and pediatric populations.
The Universal Screw Removal System is indicated to use for the removal of intact and damaged screws.

Contraindications
The Craniomaxillofacial Distraction (CMF) System, the Synthes Maxillary Distraction System, the Stainless Steel Single Vector Distraction System and the Multi-Vector Distraction System are contraindicated in patients previously sensitized to nickel.

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.
– External Midface Distractor: Neurologic damage or CSF leak, leading to death, due to cranial pins penetration.
– Choking hazards:

1. Choking hazard from the extension arm being placed in the intraoral cavity and breaking as a result of interference with chewing.
2. Choking hazard due to the extension arm separating from the distractor and entering the intraoral cavity and because the surgeon does not fully tighten the extension arm to the distractor.
3. Choking hazard due to broken fragments of the flexible extension arms pinched in the soft tissue or patient rolls on extension arm while sleeping.

– Choking hazard from the silicone tube tearing or pulling off the flexible extension arm as a result of patient tampering or erosion from interference with teeth or orthodontic devices pinching in the flexible extension arm laser cuts.
– Choking hazard due to the silicone caps 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 the flexible extension arm breaking as a result of:
12. arm being pinched in soft tissue, and/or
13. patient rolls on extension arm while sleeping.
14. Re-operation due to infection at the distractor site.
15. For mandible distractors: Re-operation to repair temporomandibular joint (TMJ) degeneration.
16. Restricted/impaired bone growth requiring further surgery, because the distractor is not removed after healing of the regenerate is accomplished.
17. For mandible distractors: Re-operation because the distraction treatment does not sufficiently alleviate breathing difficulties.
18. Re-operation due to device malfunction.
19. Re-operation due to inadequate device length selected.
20. Re-operation due to device backup.
21. Re-operation due to loose distractor footplate.
22. Re-operation due to bone fracture under load.
23. For external distractors: Re-operation due to the pin migration into the bone.
24. Re-operation due to incomplete osteotomies.

Additional medical treatment for:
25. Soft tissue erosion due to the distractor componenets pressure on the soft tissue.
26. Patient pain due to end of distractor protruding into soft tissue.
27. Nerve damage requiring subsequent medical treatment.
28. Infection requiring treatment.
29. Injury of the patient due to extended OR time, because the screws/distractors can not be removed.
30. Inability to remove the extension arm from the distractor without a second incision: the extension arm that is left on the patient for the consolidation period facilitates infection requiring additional medical treatment.
31. The healing process may be altered for patients with certain metabolic diseases, with active infection or who are immune compromised.
32. Cellulitis
33. Discomfort of the patient due to long treatment duration.
34. Scar requiring revision.
35. Pain at bony generate site.
36. Cyst caused by pins.
37. Parotid gland injury.
38. For external distractors: Infection at the pins site.
39. Wound dehiscence.
40. Treatment termination due to the patient incompliance.
41. Mild anterior open bite.
42. 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.

Precautions
Preoperative Planning Precautions:
– The distractors must be placed as parallel as possible to each other and to the sagittal plane to prevent binding during actual use.
– Take care to avoid nerves, tooth buds,roots or other critical structures when drilling and/or placing screws.
– Verify for adequate bone volume and quantity for screw placement.
– When placing the distractors considered and verify:
A. Occlusal plane
B. Tooth buds and roots
C. Planned vector of distraction
D. Planned length of advancement (consider relapse and overcorrection)
E. Adequate bone volume and quantity for screw placement.
F. Location of nerves
G. Lip closure
H. Soft tissue coverage
I. Location of extension arm
J. Patient pain due to distractor interference with soft tissue
K. Access to the screws based on approach
L. For mandible distractors: Placement of condyle in the glenoid fossa

Distractor Implantation Precautions:
– Factors to be considered and verified:
A. Occlusal plane
B. Tooth buds and roots
C. Planned vector of distraction. The distractors must be placed as parallel as possible to each other and to the sagittal plane to prevent binding
D. Planned length of advancement (consider relapse and overcorrection)
E. Adequate bone volume and quantity for screw placement.
F. Location of nerves
G. Lip closure
H. Soft tissue coverage
I. Location of extension arm
J. Patient pain due to distractor interference with soft tissue
K. Access to the screws based on approach
L. For mandible distractors: Placement of condyle in the glenoid fossa

Cut and Contour of Footplates:
– Footplates should be cut so that the integrity of the screw hole is not compromised.
– Use the file or the rasp on the cutter to deburr any sharp edges.

Attachment of Extension Arm:
– 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.
– When attaching the extension arm, rotate only the collar of the removal instrument. Do not allow the base of the removal instrument to rotate in your hand, as doing so will prevent the extension arm from opening.
– 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:
– Drill rate should never exceed 1800 RPM. Higher rates can result in thermal necrosis of the bone, and an oversized hole to be drilled. The detriments of an oversized hole include reduced pullout force, increased ease of screws stripping

in bone, and/or suboptimal fixation. Always irrigate adequately during drilling to prevent overheating of the drill bit or the 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.
– If locking screws are used screw holes must be drilled perpendicular to the plate hole to prevent the screws from becoming cross threaded. A drill sleeve is provided to facilitate proper placement.
– 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.
– Do not fully tighten the screws before making theosteotomy.

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
– If the distractor is placed with the extension arm in the intraoral cavity, ensure that the extension arm does not interfere with patient's ability to chew.
– Screws can loosen during the course of treatment if placed in poor quality bone.
– Drill rate should never exceed 1800 RPM. Higher rates can result in thermal necrosis of the bone, and an oversized hole to be drilled. The detriments of an oversized hole include reduced pullout force, increased ease of screws, stripping in bone, and/or suboptimal fixation. Always irrigate adequately during drilling to prevent overheating of the drill bit or the bone.
– If locking screws are used screw holes must be drilled perpendicular to the plate hole to prevent the screws from becoming cross threaded. A drill guide is provided to facilitate proper placement.
– 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.
– Craniomaxillofacial Distractor: A minimum of three screws should be inserted through each footplate to ensure adequate stability.
– External Midface Distractor: use a minimum of 6 screws, 3 per maxillary footplate and use a minimum of 6 fixation screws, 3 per side.
– Internal Midface Distractor: Each footplate should contain a minimum of four screws for adequate stability.
– Maxillary Distractor: At least three screws must be used in each footplate to ensure adequate stability.
– Alveolar Distractor: 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.
– Screws must be placed in the holes closest to the distractor body for adequate device stability.
– Drill and insert screws closest to the osteotomy first.

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.

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.

Repeat steps for bilateral procedures.
– The distractors must be placed as parallel as possible to each other and to the sagittal plane, to prevent binding.

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.

Extension Arm Removal:
– When removing the extension arms, rotate only the collar of the removal instrument. Do not allow the base of the removal instrument to rotate in your hand, as doing so may cause a change in the distraction distance that was achieved.

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

Instrument Precaution:
– Instrument tips may be sharp, handle with care.

Warnings

Preoperative planning:
– When selecting patients for treatment with mandibular distraction, the surgeon should take into account any pre-existing conditions such as central apnea, multi-level airway obstruction, severe reflux or other etiologies of airway obstruction that are not tongue based and would not respond to advancement of the mandible. Patients with these conditions may require a tracheostomy.
– If the extension arm is placed partially in the intraoral cavity, it presents a chocking hazard, if it disengages from the distractor or breaks.
– Tooth movement may affect treatment outcomes and should be carefully considered when using an intraoral splint.

Distractor Implantation:
– Select the right/left distractor for the right/left side of the mandible in order to limit the intraoral placement of the extension arm.
– If the extension arm is placed partially in the intraoral cavity, it presents a chocking hazard, if it disengages from the distractor or breaks.
– Do not implant a distractor if the footplates have been damaged by excessive bending.
– External Midface Distractor Warnings:
  – 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 before tightening the pins, to ensure equal force distribution.
  – Patients should be advised to avoid high risk activities, as serious injury can occur if the patient falls on the device.

Internal Midface Distractor Warnings:
– 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.

– Alveolar Distractor Warnings:
  – Pliers should be used to hold the distractor by its footplates only. Holding the distractor barrel with pliers may damage the distractor.
  – Repeated bending can damage the footplates.
  – Care should be taken to not overtighten the green fixation screw as it may damage the distractor.

– Titanium Single Vector Distractor Warnings:
  – Turning the distractor body more than 4 turns at this stage can result in a partial release of the footplate that can prevent proper device release and removal.
– Craniomaxillofacial Distractor Warnings:
  – When removing the extension arms, rotate only the collar of the removal instrument. Do not allow the base of the removal instrument to rotate in your hand, as doing so may result in a change in the distraction distance that has been achieved.

Attachment of extension arm:
– The removal instrument must be used to fullytighten the extension arm to the distractor. If the removal instrument is not used, the extension arm may separate from the distractor unintentionally.

Confirmation of device activation:
– If the silicone tip guard is used to protect the end of the extension arm, it presents a choking hazard, if it becomes lose and it disengages from the extension arm or pins.

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.

General Warning
– 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

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

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 (except Multi-Vector Distractor)
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. Use the rasp on the cutter to deburr any sharp edges. Contour the footplates to the bone using the bending pliers.he
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 at this point, to avoid compromising bone integrity.
8. Unscrew and remove the distractor. Perform the corticotomy.
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.

PLACING THE MULTI-VECTOR DISTRACTOR
1. Make an intraoral incision Make an intraoral incision along the line of the mandible, exposing the buccal surface. Subperiostial exposure is recommended. Reevaluate the bony anatomy and confirm that the arm lengths are suitable. If necessary, the distractor arms may be exchanged for other lengths.
2. Mark the approximate site of the osteotomy and pin placement on the bone. Confirm that adequate and suitable bone stock is available for placing both sets of threaded Kirschner wires with trocar point.
3. Make the transbuccal incision
   To minimize the resulting scar made by pins, pinch the skin and soft tissue between the area where the two pairs of pins will be placed. The skin should also be retracted superiorly so the pins penetrate the skin in the submandibular fold, allowing the scar to fall in a relatively inconspicuous site. Make a small transbuccal incision superior to the planned osteotomy site and bluntly dissect the soft tissue.
4. Insert the first pair of pins. Using the Wire Guide/Tissue Protector , insert the self-drilling pin closest to the planned osteotomy, taking care to avoid the tooth buds. Cut the pin using the Plate and Rod Cutter to prevent its interference with the placement of the second pin. Next, insert the pin farthest from the planned osteotomy.
5. Insert the first pair of pins Using the Wire Guide/Tissue Protector , insert the self-drilling pin closest to the planned osteotomy, taking care to avoid the tooth buds. (see optional accessory technique below). Cut the pin using the Plate and Rod Cutter to prevent its interference with the placement of the second pin. Next, insert the pin farthest from the planned osteotomy.
6. Perform the buccal osteotomy
   Using a reciprocating saw, perform the osteotomy on the buccal side of the mandible, extending into the superior and inferior cortices.
7. Final placement Before placing the distractor assembly on the pins, note that the part number on the distractor body must face the patient (toward the patient's cheek). Place the distractor assembly on the pins and tighten the pin holding clamps. Complete the osteotomy on the lingual aspect of the mandible, taking care to preserve the inferior alveolar nerve. An osteotome may be used to facilitate the fracture.
8. Adjust the device as necessary to ensure a comfortable fit. The distractor assembly position should provide easy activation for both the ramus and body portions on the device. Cut the pins to length and apply Protective Caps
9. Using the Linear Activation Instrument, activate one pin clamp to confirm mobility. Return the device to its original position.

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.
4. For mandible distractors: During the course of treatment, monitor the patient's condyles in the glenoid fossae for degenerative changes.

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.
3. 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. Craniomaxillofacial Distractor: The activation instrument can be made smaller for use in young patients by removing the blue machine screw and separating the handle extension.
6. 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.

7. 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.
8. Contact your surgeon immediately, if you loose the activation instrument.
9. 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.
10. Protect the extension arms from catching on objects that could pull the devices and cause the patient pain or injury.
11. Keep the wound area clean during treatment.
12. Maintain good oral hygiene during all phases of treatment.

Troubleshooting

Trobleshooting for the Craniomaxillofacial Distractor:

– 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.
– If the removal instrument is not available, the extension arms can be removed using the activation instrument and bending pliers. Engage the extension arm with the activation instrument. While holding the activation instrument still, use the pliers to rotate the sleeve on the extension arm counterclockwise at least 16 full turns to expose the area where the extension arm connects to the distractor. Disengage the extension arm from the distractor by pulling axially for the spring finger extension arm or with side-to-side movements for the hex pocket extension arm.

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

Additional device-specific information

Reference Number

Lot or batch number

Serial number


Manufacturer


Manufacturing date


Expiration date


Do not use when packaging is damaged

Notified body


Caution, see instructions for use


Consult instructions for use

CE
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