
Instructions for Use

Curvilinear Distraction System

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

Not all products are currently available in all markets.



Authorised Representative

DePuy Ireland UC
Loughbeg
Ringaskiddy
Co. Cork Ireland

Instructions for Use

Curvilinear Distraction System

Devices in scope:

304.095	03.500.016	317.780S	401.044.04C
311.005	03.500.018	317.820S	401.045.01C
311.006	03.500.020	400.434.01C	401.045.04C
311.007	03.500.030	400.434.04C	401.046.01C
311.011	03.500.031	400.435.01C	401.046.04C
311.012	03.500.040	400.435.04C	401.061.01C
311.013	03.500.041	400.436.01C	401.061.04C
312.140	03.500.050	400.436.04C	401.063.01C
312.154	03.500.051	400.438.01C	401.063.04C
312.220	03.500.070	400.438.04C	401.065.01C
313.251	03.500.071	400.440.01C	401.065.04C
313.252	03.500.100	400.442.01C	401.291.01C
313.253	03.500.101	400.454.01C	401.291.04C
313.254	03.503.039	400.454.04C	401.292.01C
313.805	04.315.104	400.455.01C	401.292.04C
313.806	04.315.108	400.455.04C	401.294.01C
313.917	04.315.112	400.456.01C	401.294.04C
314.491	04.315.125	400.456.04C	401.295.01C
314.675	04.315.127	400.484.01C	401.295.04C
316.236	04.315.132	400.485.01C	401.296.01C
316.410	04.315.744.01C	400.486.01C	401.296.04C
316.446	04.315.746.01C	400.488.01C	401.791.01C
316.447	04.315.748.01C	400.490.01C	401.792.01C
316.448	04.315.750.01C	400.492.01C	401.794.01C
316.451	04.315.752.01C	401.041.01C	401.795.01C
316.452	04.315.764.01C	401.041.04C	401.796.01C
316.453	04.315.766.01C	401.043.01C	61.502.823
316.510	04.315.768.01C	401.043.04C	68.315.002
316.520	04.315.770.01C	401.044.01C	68.500.201
316.521	04.315.772.01C		
316.710	04.315.824.01C		
317.640	04.315.826.01C		
317.660	04.315.828.01C		
317.680	04.315.828.01C		
317.720	04.315.830.01C		
317.740	04.315.832.01C		
317.760	04.315.845.01C		
317.780	04.315.846.01C		
317.820	04.315.848.01C		
319.520	04.315.850.01C		
347.901	04.500.018		
347.964	04.500.100		
347.965	04.500.101		
347.980	04.500.130		
347.981	04.500.131		
347.986	04.500.140		
347.987	04.500.141		
391.952	04.500.150		
391.965	04.500.151		
397.211	04.500.170		
397.213	04.500.171		
397.232	04.500.200		
397.417	04.500.201		
397.420	04.500.218		
397.422	04.500.230		
397.423	04.500.231		
397.424	04.500.240		
397.430	04.500.241		
397.433	04.500.250		
01.500.201	04.500.251		
01.500.202	04.500.251		
01.500.203	04.500.270		
01.500.204	04.500.271		
01.500.205	316.446S		
01.500.208	316.447S		
03.307.002	316.448S		
03.315.003	316.451S		
03.315.004	316.452S		
03.315.007	316.453S		
03.315.008	316.510S		
03.315.009	316.520S		
03.315.010	316.521S		
03.315.011	316.710S		
03.500.014	317.640S		
03.500.015	317.660S		
	317.680S		
	317.720S		
	317.740S		
	317.760S		

Introduction

The Curvilinear Distraction System offers 2 sizes of internal curvilinear bone distractors: 1.3 Curvilinear Distractors and 2.0 Curvilinear Distractors. They feature various curved tracks (Radius R = 30 mm, R = 40 mm, R = 50 mm, R = 70 mm, R = 100 mm) and straight tracks. The distractors have transport and fixed footplates with holes for screws: \varnothing 1.3 mm bone screws for 1.3 Curvilinear Distractors and \varnothing 2.0 mm bone screws for 2.0 Curvilinear Distractors. Each size distractor is available in right and left versions. The activation gear worm propels the transport footplate along the curved track. The gear worm is located in the distractor housing and it is activated by a hex driver activation instrument. All distractors are capable of distraction lengths of maximum 35 mm.

Implants are for single use only and provided nonsterile.

The Curvilinear Distractor is made up of a single component. The distractor is packed individually using an appropriate package.

Important note for medical professionals and operating room staff: These instructions for use do not include all the information necessary for selection and use of a device. Please read the instructions for use and the Synthes brochure "Important Information" carefully before use. Ensure that you are familiar with the appropriate surgical procedure.

Materials

Implant(s): Material(s): Standard(s):

Distractor Assembly

Ti-15Mo ASTM F 2066

TAN ISO 5832-11/ASTM F1295

Co-20Cr-15W-10Ni ISO 5832-5/ASTM F90

Bone Screws

TAN ISO 5832-11/ASTM F1295

Flexible Extension Arms

Co-Ni-Cr-Mo ISO 5832-6/ASTM F562 (new style)

Co-20Cr-15W-10Ni ISO 5832-5/ASTM F90 (old style)

Silicone Rubber ASTM F 2042

Rigid Extension Arms

Co-20Cr-15W-10Ni ISO 5832-5/ASTM F90

TAN ISO 5832-11/ASTM F1295

Intended Use

The Curvilinear Distraction System is intended for use as a bone stabilizer and lengthening (and/or transport) device.

Indications

The Curvilinear Distraction System is indicated for correction of congenital deficiencies or posttraumatic defects of the mandibular body and ramus where gradual bone distraction is required.

The Curvilinear Distractor 2.0 is intended for use in adult and pediatric patients more than 1 year old.

The Curvilinear Distractor 1.3 is intended for use in pediatric patients 4 years of age and younger.

The Curvilinear Distraction System is intended for single use only.

Contraindications

Use of the Curvilinear Distraction System is contraindicated in patients sensitive to nickel.

Patient Target Group

The Curvilinear Distraction System is indicated for correction of congenital deficiencies or posttraumatic defects of the mandibular body and ramus where gradual bone distraction is required.

The Curvilinear Distractor 2.0 is intended for use in adult and pediatric patients more than 1 year old.

The Curvilinear Distractor 1.3 is intended for use in pediatric patients 4 years of age and younger.

Intended User

This IFU alone does not provide sufficient background for direct use of the device or system. Instruction by a surgeon experienced in handling these devices is highly recommended.

This device is intended to be used by qualified health care professionals e.g. surgeons, physicians, operating room staff, and individuals involved in preparation of the device. All personnel handling the device should be fully aware of the IFU, the surgical procedures, if applicable, and /or the Synthes 'Important Information' brochure as appropriate.

Implantation is to take place according to the instructions for use following the recommended surgical procedure. The surgeon is responsible for ensuring that the device is suitable for the pathology/condition indicated and that the operation is carried out properly.

Expected Clinical Benefits

Expected clinical benefits of internal distraction osteogenesis device such as the Curvilinear Distraction System when used according to the instructions for use and recommended technique are,

- Bone stabilizer
- Lengthening (and/or transport) device

Performance Characteristics of the Device

The Curvilinear Distraction System is designed to gradually lengthen the mandibular body and mandibular ramus.

Potential Adverse Events, Undesirable Side Effects and Residual Risks

As with all major surgical procedures, risks, side effects and adverse events can occur. While many possible reactions may occur, some of the most common include: Problems resulting from anesthesia and patient positioning (e.g. nausea, vomiting, neurological impairments, etc.), thrombosis, embolism, infection or injury of other critical structures including blood vessels, excessive bleeding, damage to soft tissues incl. swelling, abnormal scar formation, functional impairment of the musculoskeletal system, pain, discomfort or abnormal sensation due to the presence of the device, allergy or hyperreactions, side effects associated with hardware prominence, loosening, bending, or breakage of the device, mal-union, non-union or delayed union which may lead to breakage of the implant, reoperation.

Device Specific Adverse Events

Device specific adverse events include but are not limited to:

The adverse events for both the 1.3 and 2.0 Curvilinear Distractors could be classified in 3 major groups: choking hazard, reoperation and additional medical treatment.

Single Use Device



Do not re-use

Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.

Re-use or clinical 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 and Precautions

Precautions

- The distractors must be placed as parallel as possible to each other and to the sagittal plane to prevent binding or not turning freely during actual use.
- Take care to avoid nerves, tooth buds and roots when drilling and/or placing screws.
- Verify for adequate bone volume and quantity for screw placement.
- A minimum of four \varnothing 1.3 mm screws (for the Curvilinear Distractor 1.3) and a minimum of two \varnothing 2.0 mm screws (for the Curvilinear Distractor 2.0) are required on each side of the osteotomy.
- Factors to be considered and verified:
 - Occlusal plane
 - Tooth buds and roots
 - Planned vector of distraction
 - Planned length of advancement (consider relapse and overcorrection)
 - Adequate bone volume and quantity for screw placement
 - Location of inferior alveolar nerve
 - Lip closure
 - Soft tissue coverage
 - Location of extension arm
 - Patient pain due to distractor interference with soft tissue
 - Access to the screws based on approach
- a. For an intraoral/transbuccal approach, it is recommended to use screw holes superior to the track because it is difficult to see and access the screw holes in the inferior footplate
- b. For an external approach, it is recommended to use screw holes inferior to the track
 - Placement of condyle in the glenoid fossa
- Do not contour the bending template track. The bending template and distractor will not function properly if the track is bent.
- 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.
- Failure to crimp the track after cutting it may result in separation of the distractor assembly.
- Consider relapse/overcorrection before cutting the track to the desired length.
- After implant placement is complete, discard any fragments or modified parts in an approved sharps container.
- During the distraction process, the distractor transport footplate and extension arm will advance with the mandible and be pulled into the soft tissue. 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.
- Disengaging the Raised Head screwdriver blade from the screw by rocking the blade off the screw in the bone and/or screw module may cause the screw head to break off in the blade.
- Raised Head Screw geometry does not allow for engagement with the holding sleeve.
- The Raised Head screwdriver blade geometry does not allow for use with the pediatric trocar system. The universal trocar may be used instead.
- A minimum of 4 screws (for the 1.3 distractor) and a minimum of 2 screws (for the 2.0 distractor) are required on each side of the osteotomy.
- To increase distractor stability in thin bone, insert screws bicortically. In addition, more screws can be used.
- Do not fully tighten the screws before making the osteotomy.
- Always irrigate adequately during drilling to prevent overheating of the drill bit and bone.

- Irrigate and apply suction for removal of debris potentially generated during implantation or removal.
- Avoid damaging the plate threads with the drill.
- Take care to avoid nerves, tooth buds, tooth roots, or other critical structures when drilling and/or placing screws.
- 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.
- Distractors, instruments, and screws may have sharp edges or moving joints that may pinch or tear user's glove or skin.
- Handle devices with care and dispose of worn bone-cutting instruments in a sharps container.
- Use appropriate screw length to avoid distractor loosening or damage of critical/lingual structures.
- Activate the distractor counterclockwise a half turn prior to drilling and/or inserting screws to ensure adequate distance between the screw holes and the osteotomy.
- If locking screws are used (2.0 distractor only), 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.
- Ensure there is adequate bone for screw placement in the desired location. Screws can loosen during the course of treatment if placed in poor quality bone because disengagement of the screws may pull screws out of bone.
 - Firmly press the screwdriver blade into the screw recess to ensure retention of the screw on the screwdriver blade.
- 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.
- Applying too much torque to the screws may cause implant and/or instrument breakage, deformation, or bone stripping.
- 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 the nerve.
- 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.
- In case of bilateral procedure, the distractors must be placed as parallel as possible to each other and to the sagittal plane, to prevent binding or not turning freely.
- 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.
- 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/care givers to follow the distraction protocol, keep the wound area clean during treatment and contact their surgeon immediately if they lose the activation instrument.
- 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.
- To avoid implant migration the distractor construct should be removed after treatment.
- Screw heads might become obscured by bone or tissue ingrowth. It may be necessary to remove this ingrowth before screw removal.
- Device/Distractor might have distracted away from the incision site. It may be necessary to extend the existing incision or create a new incision for access to screws for removal.
- After implant placement or removal is complete, the surgical area should be irrigated and suction should be applied for removal of debris potentially generated during the procedure.

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.
- When selecting patients for treatment, ensure there is adequate bone for distractor placement in the desired location. Poor distractor placement or distractor placement on poor quality bone can cause surgical delay, device loosening, poor resulting joint mechanics, ankylosis, malunion or non-union, soft tissue irritation or damage, damage to surrounding organs and structures, and bone damage, as well as possible distraction relapse or over-correction. In the neonatal patient, it is at the surgeon's discretion to assess the quality of the bone.
- 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.
- When selecting patients for treatment with distraction, the surgeon should take into account any pre-existing conditions such as metal allergy and foreign body sensitivity.
- If the extension arm is placed partially in the intraoral cavity, it presents a choking hazard, if it disengages from the distractor or breaks.
- Metallic internal fixation devices cannot withstand activity levels and/or loads equal to those placed on normal healthy bone as these devices are not designed to withstand the unsupported stress of full weight-bearing or load-bearing.
- Bending templates (2.0 distractor only) should not be used as drill guides for implanting the actual distractor on the patient. Doing so may release non-bio-compatible aluminum fragments into the wound site.
- Discard the bone screws after the bending templates are removed from the bone model.
- Select the right/left distractor for the right/left side of the mandible in order to limit the intraoral placement of the extension arm.
- Do not implant a distractor if the footplates have been damaged by excessive bending.
- Instruments and screws may have sharp edges or moving joints that may pinch or tear user's glove or skin.
- Do not contour the distractor track, as doing so may damage the distractor.
- 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.
- The removal instrument must be used to fully tighten the extension arm to the distractor. If the removal instrument is not used, the extension arm may separate from the distractor unintentionally.
- Ensure screw insertion at a right angle to the footplate. Off-axis screw insertion may result in improper screw engagement in bone which might lead to a choking hazard.
- Use of an inappropriate size screw or drill bit may lead to screw pull out and cause an obstruction or a choking hazard.
- Do not use the Raised Head screwdriver blade to insert screws in patients with poor bone quality because disengagement of the screws may pull screws out of bone.
- In poor quality bone, it is recommended to use the PlusDrive screwdriver blade when inserting Raised Head Screws with limited retention, to prevent screw pullout after insertion due to retention forces between the Raised Head Screws and Raised Head screwdriver blades.
- When the distractor is placed and/or removed intraorally, use of a throat pack is required to prevent a choking hazard in case of implant fragments generated during the surgery.
- Take care to remove all fragments that are not fixated during surgery.
- Instruments should be inspected after processing and worn devices should not be used.
- Ensure appropriate screw length to avoid distractor loosening or damage of other critical/lingual structures.
- Drill rate should never exceed 1,800 rpm. Higher rates can result in thermal necrosis of the bone, soft tissue burns, and an oversized hole to be drilled. The detriments of an oversized hole include reduced construct stability, increased ease of the screws stripping in bone, and/or suboptimal fixation.
- If the silicone tip guard is used to protect the end of the extension arm, it presents a choking hazard, if it becomes loose and it disengages from the extension arm.

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 F2052-061 and ASTM F2119-07

Non-clinical testing of a worst case scenario in a 3 T MRI system did not reveal any relevant torque or displacement of the construct for an experimentally measured local spatial gradient of the magnetic field of 70.1 T/m. The largest image artifact extended approximately 55 mm from the construct when scanned using the Gradient Echo (GE). Testing was conducted on a 3 T MRI system.

Radio Frequency (RF) – induced heating according to ASTM F2182-11a

Non-clinical electromagnetic and thermal simulations of a worst case scenario lead to temperature rises of 19.5 °C (1.5 T) and 9.78 °C (3 T) under MRI Conditions using RF Coils (whole body averaged specific absorption rate [SAR] of 2 W/kg for 15 minutes).

Precautions

The above mentioned test relies on non-clinical testing. The actual temperature rise in the patient will depend on a variety of factors beyond the SAR and time of RF application. Thus, it is recommended to pay particular attention to the following points:

- It is recommended to thoroughly monitor patients undergoing MR scanning for perceived temperature and/or pain sensations.
- Patients with impaired 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

Preoperative planning

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.

Select the appropriate distractor size based on patient age and anatomy. The Curvilinear Distractor 1.3 is intended for use in pediatric patients 4 years of age and younger. The Curvilinear Distractor 2.0 is intended for use in adult and pediatric patients more than 1 year old. For patients 1–4 years old either size distractor can be used. Selection should be based on the size of the mandible.

Correct placement and orientation of osteotomies and distraction devices is critical to successful treatment with curvilinear distraction.

Synthes offers two options:

1 Synthes ProPlan CMF

ProPlan CMF is a computer-aided surgical planning service for preoperative case visualization, which includes patient specific surgical guides to transfer the plan to the operating room.

Getting started with ProPlan CMF

There are several options for getting more information or initiating a case:

- Contact your local DePuy Synthes CMF sales representative
- Website: www.trumatchcmf.com
- Email: RA-DPYCH-psi@ITS.JNJ.com
- Phone: +41 61 965 61 66

2 Bending templates for bone model surgery

Bending templates are available in the set and they should be used prior to the surgery date for case planning and model surgery. They are available for the 2.0 Curvilinear Distractor only. They are not available for the 1.3 Curvilinear Distractor.

Distractor Implantation

The following surgical technique is an example of external approach with the distractor positioned so that the extension arm exits through a percutaneous activation port.

1. Make incision submandibular

Make a mandibular vestibular incision. Elevate the periosteum to expose the mandible.

2. Mark osteotomy

Mark the approximate site of the osteotomy.

3. Fit distractor

Place a distractor in the intended area to assess the patient's anatomy and determine the approximate location of the footplates, bone screws and extension arm. If the distractor was not cut and contoured preoperatively, the device must be fitted to the mandible intraoperatively.

4. Cut and contour footplates

Cut the footplates using the cutter to remove any unnecessary screw holes. Screw holes above and below the distractor track provide flexibility in screw placement. It is not necessary to place screws in all four footplates. To access all areas of the footplates with the cutter, it is helpful to advance the distractor at least 5 full turns and flip the distractor upside down so the U-joint does not interfere with the cutter. Return the distractor to the undistracted position after cutting. Cut the footplates so the cut edges are flush with the distractor. Contour the footplates to the mandible using the combined pliers.

5. Cut and crimp distractor track

The distractor track allows for 35 mm of advancement. If less advancement is required, cut the distractor track to the desired length according to the treatment plan. The underside of the distractor track is etched to indicate the cutting location in order to achieve the desired length of advancement. These marks take into account the 2 mm length of the crimp. If the track is cut, it must be crimped to prevent separation of the distractor assembly. Engage the crimping instrument with the track and follow the orientation instructions etched on the instrument.

6. Attach extension arm

Select the appropriate length extension arm (flexible or rigid) based on the planned amount of distraction and the desired location of the activation hex. The activation hex is the part of the device that engages the activation instrument. There are two versions of flexible extension arms and they attach differently to the distractor. If the extension arm is etched with the Synthes logo on the outer sleeve, it attaches to the distractor with spring fingers. If the flexible extension arm is etched with a line on the activation hex, it attaches to the distractor with a hex pocket. The instructions for use below provide details for both versions of flexible extension arm. Engage the removal instrument with the hex on the flexible extension arm. Rotate the removal instrument collar counterclockwise at least 16 full turns until the spring fingers or the hex pocket on the opposite end of the extension arm are exposed. For the hex pocket extension arm, place the distractor body activation hex into the hex pocket of the extension arm. Rotate the removal instrument collar clockwise until the extension arm closes over the activation hex on the distractor and fully tighten. Visually verify that the flange of the extension arm is contacting the collar of the U-joint. Rigid extension arms are also available and they attach to the distractor with the hex pocket coupling.

7. Create activation port for extension arm

A percutaneous activation port must be created in the soft tissue through which the extension arm will exit. Create the percutaneous activation port by making a stab incision through the skin, followed by blunt dissection. Place the distractor on the mandible and pull the extension arm through the percutaneous activation port using forceps.

8. Mark distractor location

Mark the distractor location before making the osteotomy by drilling and/or inserting at least one appropriate length screw at a right angle through each footplate. Use the appropriate drill bit and screwdriver shaft for the distractor size selected. Confirm drill bit length prior to drilling.

Confirm screw length prior to implantation. Use a depth gauge or screw length marker in screw module if required. Before making the osteotomy, mark the position of the distractor by drilling and/or inserting one appropriate size and length screw through each footplate. Fully seat the screwdriver blade in the screwdriver handle with hexagonal coupling before use of the screwdriver blade.

PlusDrive Screws are intended to be inserted using PlusDrive screwdriver blades. Raised Head Screws are intended to be inserted using Raised Head screwdriver blades.

Raised Head Screws also engage with the appropriate size PlusDrive screwdriver blade in the same manner as PlusDrive screws.

When using PlusDrive screwdriver blades for insertion, to engage the screw on the blade, align the appropriate size PlusDrive screwdriver blade over the cruciform recess and slowly rotate it counterclockwise until the blade drops into the recess. Firmly press the blade to fully seat it into the screw.

To engage the Raised Head Screws on the Raised Head screwdriver blade, align the internal hexagon of the appropriate size Raised Head screwdriver blade with the hexagonal head of the screws and place the tip of the blade over the head of the screw. Firmly press the blade over the screw to fully engage the screw with the blade. Do not fully tighten the screws.

To disengage the PlusDrive screwdriver blade from the screw, rock the blade off the screw and/or screw module.

To disengage the Raised Head screwdriver blade from the screw, pull the blade away from the screw axially.

Remove the distractor and footplates after marking the site.

9. Perform buccal corticotomy

Unscrew and remove the distractor. Perform the corticotomy on the buccal side of the mandible, extending into the superior and inferior borders. This allows stability of the bone segments during reattachment of the distractor. Optional Technique: It may be desirable to make a complete osteotomy prior to reattaching the distractor as it can be difficult to use an osteotome to complete the osteotomy once the distractor is reattached.

10. Reattach distractor

Use the appropriate drill bit and screwdriver shaft for the reattachment of the selected distractor size. Reattach the distractor by aligning the footplates with the holes made previously. Drill and/or insert screws at a right angle to the footplate. Fully tighten all screws, but use care not to over-tighten.

Refer to Step 8 (Mark distractor location) for guidance for screw insertion, and associated precautions, warnings, notes, technique tips, and part numbers.

11. Complete osteotomy

Complete the osteotomy on the lingual aspect of the mandible using an osteotome.

12. Confirm device activation

Use the activation instrument to engage the activation hex of the extension arm. Rotate counterclockwise, in the direction marked on the instrument handle to confirm device stability and verify movement of the mandible. Return the distractor to its original position.

Optional technique using the silicone tip:

The silicone tip guard could be used to protect the end of the extension arm.

13. Optional technique for bilateral procedures

Repeat Steps 1 through 12 on the contralateral side. Close all incisions.

Postoperative Considerations

It is recommended to begin active distraction three to five days after device placement. For patients younger than one year, active distraction can begin earlier, to prevent premature consolidation. To activate the distractors, engage the activation instrument with the extension arm and rotate counterclockwise in the direction of the arrow marked on the instrument. A minimum of 1.0 mm of distraction per day (half turn twice daily) is recommended to prevent premature consolidation. In patients one year old and younger, a rate of 1.5 to 2.0 mm per day may be considered. See: "Patient Care Guide. For the Curvilinear Distractor".

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.

Consolidation

After the desired advancement has been achieved, the new bone must be given time to consolidate. The consolidation period should be approximately six to twelve weeks. This time period may vary in relation to patient age and should be determined by clinical evaluation.

The extension arms can be removed at the start of the consolidation phase.

Implant Removal

Extension Arm Removal

There are two versions of extension arms and they are removed from the distractor differently. If the extension arm is etched with the Synthes logo on the outer sleeve, it is connected to the distractor with spring fingers. If the extension arm is etched with a line on the activation hex, it is connected to the distractor with a hex pocket. The rigid extension arms also connect with hex pocket. The instructions for use below provide details for both versions of extension arm.

Engage the removal instrument with the extension arm. Rotate the removal instrument collar counterclockwise at least 16 full turns in the direction marked "OPEN" in the collar. This will unscrew the outer sleeve of the extension arm and expose the area where the extension arm connects to the distractor.

For the spring finger extension arm, disengage the extension arm from the distractor by pulling it axially and remove the extension arm through the percutaneous port.

For the pocket extension arm, disengage the extension arm from the distractor with side-to-side movements of the arm. Remove the extension arm through the percutaneous port.

Optional technique for extension arm removal

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.

Device removal

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.

The distractors are easier to remove if the extension arms are removed before distractor removal.

For removal of screws with PlusDrive screwdriver blades, use the appropriate screwdriver blade for the footplate size selected.

Fully seat the screwdriver blade in the screwdriver handle with hexagonal coupling before use of the screwdriver blade.

When using PlusDrive screwdriver blades for removal, to engage the screw on the blade, align the appropriate size PlusDrive blade over the cruciform recess and slowly rotate it counterclockwise until the blade drops into the recess.

Firmly press the blade to fully seat it into the screw.

Remove the screw from the distractor footplate.

If Raised Head Screws were used, Raised Head Screwdriver Blades should be used for screw removal.

For removal of screws with Raised Head Screwdriver Blades, use the appropriate screwdriver blade for the footplate size selected.

Fully seat the screwdriver blade in the screwdriver handle with hexagonal coupling before use of the screwdriver blade.

To engage the Raised Head Screws on the Raised Head Screwdriver Blade, align the internal hexagon of the appropriate size Raised Head Screwdriver blade with the hexagonal head of the screws and place the tip of the blade over the head of the screw.

Firmly press the blade over the screw to fully engage the screw with the blade.

Remove the screw from the distractor footplate.

To disengage the screw from the blade, pull the screw axially using forceps.


Remove all screws from the distractor footplates. Remove the distractor from the treatment site and discard according to standard procedures.


For additional screw removal options refer to the *Universal Screw Removal Set* brochure (036.000.773).

Clinical Processing of the Device

Detailed instructions for processing of implants and reprocessing of reusable devices, instrument trays and cases are described in the Synthes brochure "Important Information". Assembly and disassembly instructions of instruments "Dismantling multipart instruments" are available on the website.

Additional Device-Specific Information

 Reference Number

 Lot or batch number

 Serial number

 Legal Manufacturer

 Authorized representative

 Manufacturing date

Disposal

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.

Devices must be disposed of as a healthcare medical device in accordance with hospital procedures.


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Synthes GmbH
Eimattstrasse 3
4436 Oberdorf
Switzerland
Tel: +41 61 965 61 11
www.jnjmedicaldevices.com