Instructions for Use
Curvilinear Distraction System

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Instructions for Use

CURVILINEAR DISTRACTION SYSTEM
Please read these instructions for use, the "Important Information" leaflet and the corresponding surgical techniques Curvilinear Distraction System (036.001.421 or DSEM/CMF/0915/0096) carefully before use. Ensure that you are familiar with the surgical technique.
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: ∅ 1.3 mm bone screws for 1.3 Curvilinear Distractors and ∅ 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.

Implant(s):	**Material(s):**	**Standard(s):**
Distractor Assembly	Ti-15Mo	ASTM F 2066
	TAN	ISO 5832-11
	Co-20Cr-15W-10Ni	ISO 5832-5
Bone Screws	TAN	ISO 5832-11
Flexible Extension Arms	Co-Ni-Cr-Mo	ISO 5832-6
	Silicone Rubber	ASTM F 2042
Rigid Extension Arms	Co-20Cr-15W-10Ni	ISO 5832-5
	TAN	ISO 5832-11

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.

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.

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 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, re-operation and additional medical treatment.

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
- 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 and roots when drilling and/or placing screws.
- Verify for adequate bone volume and quantity for screw placement.
- A minimum of four ∅ 1.3 mm screws (for the Curvilinear Distractor 1.3) and a minimum of two ∅ 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 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.
- 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.
- Avoid damaging the plate threads with the drill.
- 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.
- Activate the distractor counterclockwise (open) 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 (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.
- Use the appropriate screw length to avoid damage of lingual structures.
- Do not fully tighten the screws before making the osteotomy.
- To increase distractor stability in thin bone, insert screws bicortically. In addition, more screws can be used.
- 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.
- 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.
- 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.
- 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.
- 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 should be removed after treatment.

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 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.
- Bending templates should not be used as drill guides for implanting the actual distractor on the patient. Doing so may release nonbiocompatible 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.
- 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.
- 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.
- If bending templates were used for preoperative planning (for the 2.0 Curvilinear Distractor only) they should not be used as drilling guides on the patient. Doing so may accidentally release nonbiocompatible aluminum fragments into the wound site.
- 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.

Magnetic Resonance environment
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 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.

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 Synthes sales representative
– Website: www.synthescss.com
– Email: csspdeu@synthes.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 an intraoral approach with the distractor placed in a posterior orientation with 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.
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**
   Use the appropriate drill bit and screwdriver shaft for the distractor size selected. Before making the osteotomy, mark the position of the distractor by drilling and/or inserting one appropriate size and length screw through each footplate.
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 the remaining appropriate size and length screws. Fully tighten all screws.
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.

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.

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

The implant components applied (name, article number, lot number) must be documented in each patient's record.
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.

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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