Instructions for Use
Curvilinear Distraction System

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

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 001273 SE_475753 AC 08/2014

Instructions for Use

CURVILINEAR DISTRACTION SYSTEM
Please read these instructions for use, the Synthes brochure "Important Information" and the corresponding surgical techniques Curvilinear Distraction System (036.001.421) carefully before use. Ensure that you are familiar with the appropriate surgical technique.
The Synthes 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.

Material(s)
Material(s): Standard(s):
The Curvilinear Distractor assembly is made of titanium alloys (Ti-15Mo per standards ASTM F 2066 and TAN per ISO 5832-11) and L605 (Co-20Cr-15W-10Ni per standard ISO 5832-5).
The bone screws are made of titanium alloy (TAN per standard ISO 5832-1).
The flexible extension arms are made of MP35N (Co-Ni-Cr-Mo per standard ISO 5832-6) and their silicone rubber (per standard ASTM F 2042).
The rigid extension arms are made of L605 (Co-20Cr-15W-10Ni per standard ISO 5832-5).
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 Synthes Curvilinear Distraction System is intended for use as a bone stabilizer and lengthening (and/or transport) device.

Indications
The Synthes 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 Synthes Curvilinear Distraction System is intended for single use only.

Contraindications
Use of the Synthes Curvilinear Distraction System is contraindicated in patients sensitive 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.
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.
Choking hazard
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
4. 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.
5. Choking hazard due to the silicone caps used to protect the end of the activation hex coming unfastened due to rubbing.

The healing process may be altered for patients with certain metabolic diseases, with active infection or who are immune compromised.

Re-operation
1. Reoperation because the distractor is not crimped by the surgeon in the OR and it will disengage from the track collapsing the new generated bone.
2. Re-operation because the distractor system breaks or disengages due to patient excessive activities
3. Re-operation because the footplate breaks after implantation surgery, during treatment due to decreased strength as a result of excessive bending of the footplate during implantation.
4. Re-operation because the footplate breaks postoperatively prior to bone consolidation process is completed due to an excessive strain by the patient.
5. Re-operation to remove device due to allergic reaction to device material/biological sensitivity to nickel.
6. Non-union leading to re-operation (worst case) because the number of screws used with the footplates is not sufficient.
7. Re-operation due to the screw migration in thin bone.
8. Premature bone consolidation requiring reoperation due to the distractor being activated in the wrong direction after being activated in the proper direction.
9. Re-operation to correct the regenerate bone due to the distractor being positioned along incorrect vectors as a result of incorrect vector planning or difficulties transferring the treatment plan to surgical placement.
10. Re-operation to replace the device due to device disturbance by traumatic patient injury not related to procedure or treatment.
11. Restricted/impaired bone growth requiring further surgery because the distractor is not removed after healing is accomplished.
12. Re-operation due to the flexible extension arm breaking as a result of:
    – arm being pinched in soft tissue, and/or
    – patient rolls on extension arm while sleeping.
13. Re-operation due to relapse.
14. Re-operation to repair temporomandibular joint (TMJ) degeneration.
15. Restricted/impaired bone growth requiring further surgery, because the distractor is not removed after healing of the regenerate is accomplished.
16. Re-operation because the distraction treatment does not sufficiently alleviate breathing difficulties.

Additional medical treatment
1. Soft tissue erosion due to the extension arm pressure on the soft tissue
2. Patient pain due to end of distractor track protruding into soft tissue.
3. Nerve damage requiring subsequent medical treatment.
4. Infection requiring treatment due to the inability to remove the extension arm
5. Injury of the patient due to extended OR time, because the screws can not be removed
6. 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.

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
– 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 include:

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. 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) is required on each side of the osteotomy
F. Location of inferior alveolar nerve
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
   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

L. 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.

Distractor Implantation

– 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. 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
F. Location of inferior alveolar nerve
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
   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

L. Placement of condyle in the glenoid fossa

Cut and contour 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.

Cut and crimp distractor track

– Failure to crimp the track after cutting it may result in separation of the distractor assembly.
– Use the file or the rasp on the cutter to deburr any sharp edges.
– Consider relapse/overcorrection before cutting the track to the desired length.

Attach extension arm

– 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.
– 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.

Mark 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 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 sleeve is provided to facilitate proper placement.
– Take care to avoid nerves, tooth buds and roots when drilling and/or placing screws.
– Use the appropriate screw length to avoid damage of lingual structures.
– Do not fully tighten the screws before making the osteotomy.

Reattach 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 when drilling and/or placing screws.
– 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, (2.0 Curvilinear 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.
– 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 damage of lingual structures.

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 the nerve.

Confirm 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.

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.
– 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.

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.

Cut and crimp distractor track
– Do not contour the distractor track, as doing so may damage the distractor.

Attach extension arm
– 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.

Mark distractor location
– 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.

Confirm 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.

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.
– 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.

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. 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.
3. Correct placement and orientation of osteotomies and distraction devices is critical to successful treatment with curvilinear distraction. Options for preoperative planning include computer assisted planning with Synthes ProPlan CMF and bone model surgery.
4. Synthes ProPlan CMF planning service allows:

– Live interactive planning session with a knowledgeable support team
– The surgeon to make critical clinical decisions preoperatively
– 2D and 3D visualization of preoperative patient anatomy and condition (to avoid inserting screws into nerves and tooth buds and roots)
– Cephalometric analysis
– Simulation of skeletal osteotomies
– Visualization of movement of osteotomized bone structures (mandibular movement to desired posteroperative position)
– Identification of potential bone interferences
– Virtual placement of the distractor on the mandible to determine the proper distractor size, radius and placement
– Visualization of the clinical plan to validate the planned, clinical result
– Soft tissue simulation and (3D) photomapping

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

– Contact your local DePuy Synthes sales representative
– Website: www.synthescss.com
– Email: csspdeu@synthes.com
– Phone: +41 61 965 61 66

6. 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.

PLACING DISTRACTORS

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 a mandibular vestibular incision. Elevate the periosteum to expose the mandible.
2. Mark the approximate site of the osteotomy.
3. Fit the distractor. Place a distractor in the intended area to assess the patient's anatomy and determine the approximate location of the footplates, bone screws and extension arm. Select the right/left distractor for the right/left side of the mandible in order to limit the intraoral placement of the extension arm.
4. If the distractor was not cut and contoured preoperatively, the device must be fitted to the mandible.
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 file or the rasp on the cutter to deburr any sharp edges. It is easier to access the footplates with the cutter if the distractor is flipped upside down so the u-joint is out of the way of the footplate. Contour the footplates to the mandible using the bending pliers.
6. Cut and crimp the distractor track.
   The track is crimped by the manufacturer. 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 in the instrument. To ensure that a complete crimp was achieved, advance the distractor to the end of the track and confirm that it does not separate.
7. Attach extension arm. Select the appropriate length extension arm based on the planned amount of distraction and the desired location of the hexagonal activation tip of the extension arm.
8. 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.
9. 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. It may be desirable to drill and/or insert all screws before making the osteotomy, to enable easier attachment of the distractor once the bone becomes mobile.
   Screws should not be fully tightened at this point, to avoid compromising bone integrity.
10. 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.
11. 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. 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.
12. Complete the osteotomy on the lingual aspect of the mandible using an osteotome.
13. Confirm device activation. Use the activation instrument to engage the hexagonal activation tip 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.
14. Repeat steps for bilateral procedures. Close all incisions.

LATENCY PERIOD

Begin active distraction three to five days after device placement. For young patients, active distraction can begin earlier, to prevent premature consolidation.

ACTIVATION PERIOD
1. One activation instrument full rotation equals 1.0 mm of distraction.
2. 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.
3. 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.
4. To accomplish a half-turn, rotate the activation instrument from the side with the arrow marked on it to the side with the open slot. The activation instru-

ment can be made smaller for use in young patients by removing the blue machine screw and separating the handle extension.
5. 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.
6. 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.
7. 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. 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.
2. The extension arms can 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. To accomplish a half-turn, rotate the activation instrument from the side with the arrow marked on it to the side with the open slot. 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.

Troubleshooting
- 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

Reference Number

Lot or batch number


Manufacturer


Manufacturing date


Do not use when packaging is damaged

Notified body


Caution, see instructions for use

CE
0123

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