Instructions for Use
Craniomaxillofacial (CMF) Distraction System

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

Not all products are currently available in all markets.

EC REP

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DePuy Synthes
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Instructions for Use

Craniomaxillofacial (CMF) Distraction System

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Introduction
The DePuy Synthes Craniomaxillofacial (CMF) Distraction System is a modular family of internal distraction osteogenesis devices that are used to gradually lengthen the mandibular body, mandibular ramus, and cranium. Each device, when assembled, is comprised of a distractor body, two footplates, and a machine screw to secure the assembly. The system also includes optional extension arms, which can be attached to the activation end of the device to move the point of activation to an area accessible by the activation instrument.
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)
CP Ti	ASTM F 67	ISO 5832-2
TAN	ASTM F 1295	ISO 5832-11
L605	ASTM F 90	ISO 5832-5
MP35N	ASTM F 562	ISO 5832-6
CoCrMo	ASTM F1537	ISO 5832-12
Silicone	ASTM F 2042	n/a

Intended Use
The DePuy Synthes CMF Distraction System is intended for use as a bone stabilizer and lengthening (and/or transport) device.

Indications
The DePuy Synthes CMF Distraction System is indicated for correction of congenital deficiencies or post-traumatic defects of the mandibular body, mandibular ramus, and cranium where gradual bone distraction is required in adults and pediatric patients. DePuy Synthes CMF Distraction System is intended for single use only.

Mandible
- The 1.0 mm footplates and screws are intended for neonates and infants under the age of 12 months
- The 1.3 mm footplates and screws are intended for neonates, infants, and children 4 years of age and younger
- The 1.5 mm and 2.0 mm footplates and screws are intended for infants, children, adolescents, and adults 1 year of age and older

Cranium
- The 1.5 mm and 2.0 mm mesh and cloverleaf footplates and screws are intended for infants, children, adolescents, and adults

Contraindications
Use of the DePuy Synthes CMF Distraction System is contraindicated in patients previously sensitized to nickel, cobalt chromium, silicone, or molybdenum

Patient Target Group
The DePuy Synthes CMF Distraction System is indicated for correction of congenital deficiencies or post-traumatic defects of the mandibular body, mandibular ramus, and cranium where gradual bone distraction is required in adults and pediatric patients.

Mandible
- The 1.0 mm footplates and screws are intended for neonates and infants under the age of 12 months
- The 1.3 mm footplates and screws are intended for neonates, infants, and children 4 years of age and younger
- The 1.5 mm and 2.0 mm footplates and screws are intended for infants, children, adolescents, and adults 1 year of age and older

Cranium
- The 1.5 mm and 2.0 mm mesh and cloverleaf footplates and screws are intended for infants, children, adolescents, and adults

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 Craniomaxillofacial (CMF) 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 Craniomaxillofacial (CMF) Distractor is designed to gradually lengthen the mandibular body, mandibular ramus, and cranium.

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, dental injuries, neurological impairments, etc.), thrombosis, embolism, infection, cerebrospinal fluid leak, nerve and/or tooth root damage, injury of critical structures including the brain, dura mater, venous sinuses and other blood vessels, Temporomandibular Joint (TMJ) ankylosis and degeneration, excessive bleeding, damage to soft tissues including swelling, perioperative morbidity, abnormal scar formation, wound dehiscence, skin necrosis, 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, impairment while eating or feeding.

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.

These devices are provided NONSTERILE. Resterilization of the nonsterile device may only be performed if the device has been opened, but not used. Resterilization of the nonsterile device should not be performed if the device packaging is damaged upon receipt or if the device has been contaminated by bodily fluids.

Warnings and Precautions

Warnings

General Warnings
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 cranial distraction, the surgeon should take into account any pre-existing conditions such as non-syndromic craniosynostosis that would not be treated as a result of this procedure.

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.

Instruments should be inspected after processing and worn devices should not be used.

The manufacturer is not responsible for any complication arising from incorrect diagnosis, choice of incorrect implant, incorrectly combined implant components and/or operating techniques, the limitations of treatment method, or inadequate asepsis. The implant components applied (name, article number, lot number) must be documented in each patient's record.

These devices can break during use (when subjected to excessive forces or outside the recommended technique). While the surgeon must make the final decision on removal of the broken part based on associated risk in doing so, it is recommended that whenever possible and practical for the patient, the broken part should be removed.

Take care to remove all device fragments that are not fixated during surgery.

In cases of mandibular distraction when the distractor is placed and/or removed intraorally, use of a hospital-approved throat pack is required to prevent a choking hazard in case of device fragments generated during the surgery.

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 joint mechanics, ankylosis, malunion or nonunion, 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.

Warnings for Surgical Technique Instructions
Ensure all steps of the provided technique are followed. It presents a choking hazard if components of the distractor (e.g. bone screw, machine screw, distractor collar, universal joint, extension arm and silicone tube of flexible extension arm) become loose, disengage from the distractor, or break.

Fully tighten the machine screw to the distractor body using a two-finger tightening technique after it is assembled with the footplates, however, it is important not to overtighten as the machine screw threads may strip leading to a choking hazard.

To ensure proper function of the instrument and help prevent unintended reversing of the distractor by the patient and/or caregiver after implantation, use the surgeon activation instrument to activate the distractor for the full length of distraction prior to implantation.

If the end of the AB distractor is not assembled with the collar, there is a potential for the distractor to disassemble at the end of distraction and cause a choking hazard.

Do not cross-thread or overtighten the extension arm when closing it over the activation hex of the distractor or it will not be possible to remove the extension arm at the end of distraction. Overtightening may also cause the threads to strip, leading to a choking hazard.

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 extension arms during sleep can damage and/or break the extension arms which may lead to a choking hazard. It is advised to secure the extension arms to the patient's skin, without affecting the arms' ability to rotate. Options include suture or tape.

During the course of treatment, infection can occur at the extension arm/skin interface. Monitor the patient for symptoms of infection and inform the patient to seek medical care if area becomes painful or sees any redness or drainage from skin.

Repeat and/or reverse and sharp bending may weaken the plate and lead to premature implant failure.

Do not bend the plate beyond what is required by the anatomy as this may lead to damage of the footplates.

Do not implant a distractor if the footplates have been damaged by over-bending.

Ensure screw insertion at a right angle to the footplate. Off-axis screw insertion may result in improper screw engagement in bone which may 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 pull-out 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 hospital-approved throat pack is required to prevent a choking hazard in case of device fragments generated during the surgery.

Ensure appropriate screw length to avoid distractor loosening or damage of other critical/ lingual structures or dura.

Drill rate should never exceed 1800 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 screw stripping in bone, and/or suboptimal fixation.

The osteotomy must be complete and the bone as well as the transport disk must be mobile. The distractor is not designed nor intended to break bone and/or complete the osteotomy.

Use of an inappropriate size screw or drill bit may lead to screw pull out and cause dural injury.

Self-drilling screws have pointed tips which may damage the dura during distraction more easily than self-tapping screws which have rounded tips. Therefore, it is recommended to use self-tapping screws where there is a risk of damage to the dura.

Raised Head Screws in shorter lengths are offered in self-drilling only.

Warnings for Postoperative Considerations
Activation of the device on poor quality bone should be done with the activation end of the extension in-line with the distractor axis to avoid placing a levering force on the distractor which could cause separation of the device from the bone. In neonates and others with poor quality bone, it is recommended this activation be done by or under the supervision of the physician.

The patient activation instrument has only instruction for BC distractor advancement printed on the device. If an AB distractor was used during surgery, place the AB distraction label on the patient activation device so that the BC distractor advancement instruction is fully covered.

If the BC distractor advancement instruction is not fully covered, it may result in an increased rate of distraction and/or non-union.

Be sure to follow the instructions on the back of the AB distraction label for surface preparation of the patient activation instrument prior to applying the label.

The AB distraction label should be completely affixed to the device. If the AB label is not completely affixed, it may separate from the patient activation instrument and result in an increased rate of distraction and/or non-union. If a BC distractor was used during surgery, please discard the AB distraction label(s) provided with the patient activation device.

Carefully remove label from label sheet and place on instrument to prevent damage to the label.

Do not use damaged label. If the label is damaged, use replacement label.

Warnings for 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 result in a change in the distraction distance that has been achieved.

Precautions

General Precautions
Surgical implants must never be reused. An explanted metal implant must never be reimplanted. Even though the explanted device appears undamaged, it may have small defects and internal stress patterns which could lead to breakage.

Instruments, distractors, 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.

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.

All cut footplates should be deburred as needed by rubbing sharp corners and/or edges with the file on the cutter or with the file instrument included in the set.

Precautions for Preoperative Planning

When placing mandibular distractors consider and verify:

- Occlusal plane
- Tooth buds and roots
- Planned vector of distraction
- Planned length of advancement (consider relapse and overcorrection)
- Adequate bone quality and quantity for screw placement. A minimum of three screws (minimum of two screws for mandibular bone transport) is required on each side of the osteotomy. The distractor may be fixated with more than three screws (two screws for mandibular bone transport) per footplate. If large bone advancement is desired, the distractor with mesh footplate can be used to enable the use of more than three screws per footplate. If the 1.0 mm system is selected, at least 4 screws must be used to secure each footplate in poor quality bone to prevent screw pull-out during treatment. Of these 4 screws, at least two screws of a minimum of 6 mm length must be used in the row of screw holes closest to the distractor body.
- Location of mental nerve and inferior alveolar nerve
- Lip closure
- Soft tissue coverage
- Location of activation hex of distractor or extension arm
- Patient pain due to distractor interference with soft tissue
- Access to the screws based on approach:
  - For intraoral/transbuccal approach, it is recommended to use screw holes superior to the distractor body because it is difficult to see and access the screw holes in the inferior footplate
  - For external approach, screws can be placed inferior or superior to the distractor body
- Placement of condyle in the glenoid fossa. Ensure that the distraction plan will not create a significant condylar dislocation. During the course of mandibular treatment, monitor the patient's condyles in the glenoid fossa for symptoms of TMJ displacement (pain, clicking or locking).
- Distractor or extension arm does not interfere with mastication.
- Devices should be placed as parallel as possible to diminish the possibility of temporomandibular joint displacement. While parallel placement of the distractors is ideal, this may be difficult to accomplish considering the patient's soft tissue coverage, and could potentially lead to patient discomfort.

When placing cranial distractors consider and verify:

- Planned vector of distraction
- Planned length of advancement (consider relapse and overcorrection)
- Adequate bone quality and quantity for screw placement. A minimum of three screws is required on each side of the osteotomy. The distractor may be fixed with more than three screws per footplate. If large bone advancement is desired, the distractor with mesh footplate can be used to enable the use of more than three screws per footplate.
- Location of activation hex of distractor or extension arm
- Dura mater
- Venous sinuses and other blood vessels
- Number of distractors to be used during treatment
- Patient pain due to distractor interference with soft tissue and hair
- Type of coronal incision
- During cranial distraction, parallel placement is necessary to facilitate proper head lengthening and ultimate symmetrical anatomy. Take great care in aligning the distractors used in a parallel position while fitting to ensure proper distraction. If parallel placement is difficult to accomplish when considering the patient's soft tissue coverage and potential patient discomfort, a slight convergence is acceptable if the point of convergence is sufficiently far from the patient.
- Soft tissue coverage

Precautions for Surgical Technique Instructions

To ensure that the soft tissue does not obstruct the activation hex during distraction, the next longer size distractor body and/or extension arm may need to be used.

The screw holes on the B-style footplate should be positioned so that they point toward the activation hex and not the open end of the distractor. Assembling the device incorrectly will reduce the distraction distance possible.

Do not allow the removal instrument to rotate in your hand; doing so will prevent the extension arm from opening.

Do not grip the flexible extension arm while rotating it with the removal instrument. Gripping the extension arm with your fingers will make it difficult to rotate and cause the silicone sleeve to twist and possibly tear.

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.

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.

Location of activation port should be chosen such that the maximum curvature of the extension arm is not exceeded, as this may cause the arm to break. The extension arm should be placed in-line with the distractor body as much as possible to prevent pressure from being placed on the device and patient's bone which may cause loosening of the device from the bone (especially for patients with poor bone quality).

When inserting the flexible extension arm into the operative site, take care to protect silicone sleeve to prevent soft tissue interference during distraction.

Location of the activation port should include consideration of important structures that may lie in the path between the distractor and the skin exit site. The main trunk or branches of the facial nerve, as well as other structures, may be injured when creating this port.

The alignment rods should not be used as leverage for bending or contouring of the footplates as this may cause damage to the distractor bodies.

A minimum of three screws should be used in each footplate to ensure adequate stability. If the 1.0 mm system is selected, at least 4 screws must be used to secure each footplate in poor quality bone to prevent screw pull-out during treatment. Of these 4 screws, at least two screws of a minimum of 6 mm length must be used in the row of screw holes closest to the distractor body.

Ensure screws will have purchase in good quality bone; footplates may shift during treatment if they are not properly secured.

Contour each footplate individually while holding that footplate with the bending pliers. Avoid bending one footplate while holding either the distractor body or the other footplate.

Footplates should be cut and deburred so that the integrity of the screw hole is not compromised and tissue irritation is minimized.

Take care to avoid nerves, tooth buds, tooth roots, or other critical structures when drilling and/or placing screws.

It is recommended to separate the footplates by a minimum of 2 mm prior to drilling and/or inserting screws to ensure adequate distance between the pilot holes and the osteotomy.

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 three screws should be inserted through each distractor footplate to ensure adequate stability. It is recommended to use screw holes closest to the distractor body.

The distractor may be fixated with more than three screws per footplate. If longer bone advancement is desired, the distractor with mesh footplate could be used to enable the use of more than three screws per footplate.

To increase distractor stability in thin bone, insert screws bicortically. In addition, more screws can be used.

Always irrigate adequately during drilling to prevent overheating of the drill bit and bone.

Take care while drilling as not to 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.

Do not fully tighten the screws before completing the osteotomy.

Before making osteotomy irrigate and apply suction for removal of debris potentially generated during implantation or removal.

Use appropriate screw length to avoid distractor loosening or damage of critical/lingual structures.

If locking screws are used, screw holes must be drilled at a right angle to 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.

Use appropriate screw length to avoid distractor loosening or damage of critical structures or dura.

Applying too much torque to the screws may cause implant and/or instrument breakage, deformation, or bone stripping.

A minimum of two screws should be inserted through each distractor footplate during bone transport to ensure adequate stability. It is recommended to use screw holes closest to the distractor body. The distractor may be fixated with more than two screws per footplate. If longer bone advancement is desired, the distractor with mesh footplate could be used.
Take care to avoid the dura, vascular structures and other critical structures when drilling and/or placing screws.

4 mm length screws are recommended for use in cranial vault expansion to limit the possibility of dural injury.

To increase distractor stability in thin bone, more screws can be used to enable the use of more than three screws per footplate.

Depending on patient anatomy and placement of the distractor, the extension arm can either exit anterior or posterior. If placed anteriorly, the patient hairline should be considered to cover any potential scarring.

Precautions for Postoperative Considerations
The patient activation instrument was designed to help prevent activation of the distractor in the incorrect direction (clockwise–opposite the direction of the arrow); however, there is a possibility that the instrument can reverse the distractor when activated in the clockwise direction. Off-axis engagement of patient activation instrument with activation hex or extension arm further increases the risk of reversing distractor. Therefore, it is important to communicate to the caregiver the correct direction (counterclockwise–the direction of the arrow) and alignment for activation to prevent accidental distractor reversal which may, in severe cases, lead to obstruction of airway or increased intracranial pressure.

Ensure the patient activation instrument is always held by the handle, not the shaft, during activation. Only activation by the handle will provide enough turning force to activate the distractor.

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.

It is important to instruct patients regarding hazards, harms, and proper use of the distractor: to seek Emergency Care immediately if the patient experiences any difficulty in breathing, how to turn the distractor, to follow the distraction protocol, to follow up with appointments, to report loose or broken parts immediately to surgeon, to keep wound area clean during treatment, to maintain good oral hygiene during all phases of treatment, and to contact surgeon immediately if they lose the patient activation instrument or AB distraction label or the distractor is loose or broken and/or when the patient has changes/increased difficulty in eating.

Advise the patient not to tamper with the distractor(s) or extension arm(s) and to avoid physical activities that may interfere with treatment or device such as those that may include unexpected falls.

Ensure that the distraction plan will not create a significant condylar dislocation. During the course of mandibular treatment, monitor the patient's condyles in the glenoid fossa for symptoms of TMJ displacement (pain, clicking or locking).

Precautions for Extension Arm Removal
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.

Precautions for Device Removal
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.

To avoid implant migration, the distractor construct should be removed after treatment.

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
Magnetic Resonance Environment Torque, Displacement and Image Artifacts according to ASTM F 2213-17, ASTM F 2052-15 and ASTM F2119-07
Non-clinical testing of 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 single Siemens Prisma 3 T MRI system.
Radio-Frequency-(RF-)induced heating according to ASTM F2182-11a
Non-clinical electromagnetic and thermal simulations of worst case scenario lead to temperature rises of 9.9 °C (1.5 T) and 4.9 °C (3 T) under MRI conditions using RF Coils (whole body averaged specific absorption rate [SAR] of 1 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 MRI scanning for perceived temperature and/or pain sensations.
– Patients with impaired thermoregulation or temperature sensation should be excluded from MRI 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".

Implant Removal

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.

Troubleshooting
If the extension arm separates (the outer sleeve separates from the inner sleeve), it is possible to reassemble it. Reassemble the extension arm by inserting the inner sleeve into the outer sleeve and rotating the outer sleeve clockwise until it fully closes.

If the spring fingers do not slide over the activation hex, slightly rotate the extension arm clockwise while pushing toward the distractor to fully engage.

If parallel placement is difficult to accomplish when considering the patient's soft tissue coverage and potential patient discomfort, a slight convergence is acceptable if the point of convergence is sufficiently far from the patient.

If the dura mater or other underlying structures may have been damaged during cranial distraction, an increased latency period may be used for structures to heal before distraction begins.

Do not use damaged label. If the label is damaged, use replacement label.

If the extension arm cannot be removed, fully tighten the extension arm again by rotating the removal instrument collar clockwise (it closes the extension arm over the activation hex of the distractor).

If the extension arm removal instrument is not available, the extension arms can be removed using a surgeon activation instrument and 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 spring fingers for the flexible extension arm and the hex pocket for the rigid extension arm where the extension arm connects to the distractor. Disengage the extension arm from the distractor by pull- ing axially for the flexible extension arm or with side-to- side movement for the rigid extension arm.

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.

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.

Special Operating Instructions
It is anticipated that the DePuy Synthes CMF Distraction System will be used as follows:
1. Make standard surgical incision (intraoral or submandibular for mandible and coronal for cranial)
2. Assemble and fit the distractor
3. Make standard surgical osteotomy and mobilize the bone
4. Secure the distractor
5. Verify bone mobility by device activation
6. Close incisions

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