Instructions for Use
Transpalatal Distraction System

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

EC REP

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Instructions for Use

Transpalatal Distractor
Please read these instructions for use, the Synthes brochure "Important Information" and the corresponding surgical technique 036.001.125 carefully before use. Ensure that you are familiar with the appropriate surgical technique.
The transpalatal distractor is made up of the following components:
– Left footplate
– Right footplate
– Transpalatal Distractor Body, available in 3 widths
– Blocking Screw
– Titanium safety wires
All implant components are provided unsterile and individually packed in a transparent envelop. The titanium safety wires are a pack of two.

Material(s)

Material(s):	Standard(s):
Footplates:	TiCp, ISO 5832-02: 1999
Transpalatal Distractor Body, Blocking, Threaded Pins and Bone Screw:	TAN, ISO 5832-11: 1994
Titanium safety wires:	TiCp, ISO 5832-02: 1999

Intended use
The Synthes Transpalatal Distractor is intended for use as a bone-borne maxillary expander and retainer for surgically assisted, rapid, palatal expansion.
The Synthes Transpalatal Distractor is intended for single use only.

Indications
The Synthes Transpalatal Distractor is indicated in surgically assisted, rapid, palatal expansion (SARPE) for correction of maxillary transverse deficiencies in skeletally mature patients.

Contraindications
Treatment is contraindicated for patients with certain medical conditions.

1. For patients to which the distractor can not be anchored to the teeth with the safety wires.
2. For patients with palatal crest width (at the distractor location) smaller than 18.6 mm.
3. For patients with flat and/or scarred cleft palates.
4. For patients who suffer from gingival or periodontal diseases.
5. For patients with unsatisfactory oral hygiene.
6. For patients with a history of immune deficiency, steroid therapy, problems with blood clotting, uncontrolled endocrinological disease, rheumatic disease, bone disease, diabetic problems or cirrhosis of the liver or any other systemic or acute disease.
7. For patients who suffer from osteomyelitis or have an active infection.
8. For patients with metal allergy and foreign body sensitivity.
9. For patients previously treated with radiotherapy of the head.
10. For patients with limited blood supply and insufficient bone structure (insufficient bone quantity) or possible bone defects (insufficient bone quality) in the area in which the transpalatal distractor has to be inserted.
11. For physically unstable patients and/or if the patients have mental or neurological conditions, are severely non-compliant, and are unwilling or incapable of following postoperative care instructions.
12. For patients that suffer from psychological problems such as depressions or other types of psychopathologies.

Adverse Events
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, 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.

Device Specific Adverse Events
Morbidity related to the osteotomies for transpalatal osteodistraction may necessite medical treatment of the patient for rhinorrhea, nasal bleeding, periostitis, dermatitis, infraorbital ecchymosis, excessive postoperative edema, prolonged cheek hyperesthesia, necrosis of the palatal tissue in the area of a palatal torus, prolonged V2 branch nerve hypoesthesia, hematoma, fractures of the skull base, aneurysms, arteriocavernous fistulas, injuries involving the cranial nerves. Failure to follow postoperative care and treatment instructions can cause failure of the implant and the treatment.

Device specific adverse events include but are not limited to:
– Choking hazard due to the presence of the distractor in the oral cavity, pain, bleeding, hemorrhage, loosening, inflammatory difficulties, wound dehiscence, tissue damage, teeth damage, orbital damage, infection, lesion of the palatal, buccal displacement, asymmetric expansion, relapse.

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
– Irrigate and apply suction for removal of debris potentially generated during implantation or removal.
– Evaluate:
  – The patient teeth to ensure that the distractor could be secured on both sides with safety wires.
  – Desired vector of movement and the magnitude of the desired skeletal correction.
  – Palatal mucosa thickness.
  – Palatal bone thickness in the area of footplate placement. The bone should provide adequate strength to sustain forces during the treatment. Thin palatal bone in the sinuses areas should be avoided.
  – Anatomic abnormalities of the distraction site (e.g. low maxillary sinuses) and bone quality; especially in young patients, cleft patients and patients with edentulous maxillae.
  – Necessary space for distractor placement and movement of the activation instrument during the entire course of treatment.
  – Surgical access for osteotomy (e.g. proximity of the incisors).
– The distractor is not designed or intended to break bone and/or complete an osteotomy.
– Avoid causing damage to the palatal blood vessels and critical structures while performing an osteotomy.
– Do not compromise periodontal health or tooth vitality while performing osteotomies. A 3 to 5 mm space between the apices of the central teeth is necessary to safely perform an interdental osteotomy.
– When possible, use the tooth roots behind the footplates as additional reinforcement of palatal bone.
– Place the footplates facing each other and parallel to the teeth and occlusion line.
– Be sure to evaluate bone quality and any anatomic abnormalities of the distraction site; especially in young patients, cleft patients, and patients with overdeveloped maxillary sinuses or edentulous maxillae.
– Confirm that plate positioning allows for adequate clearance of the tooth roots and critical structures while drilling or inserting the screws.
– Do not touch the spikes underneath the footplates. Handle the footplates with the plate holder included in the set.
– Do not place the distractor in a location where it interferes with the lower teeth in occlusion.

– Symmetrically expand both threaded pins so that the central body is kept in the center/midline.
– Make sure that there is sufficient space for placement of footplates and for movement of the activation instrument during the activation period.
– Place gauze in the mouth to retain any distractor part in the event it is dropped in the mouth.
– Do not bend the footplates.
– Select the appropriate drill bits and screw lengths in order to avoid damage to the critical structures.
– Confirm the screw length before using it.
– Irrigate adequately to prevent overheating of the drill bit or the bone.
– Drill rate should never exceed 1800 rpm. Higher rates can result in thermal generated necrosis of the bone, and an oversized hole.
– Always use two screws with each footplate to ensure adequate distractor stability.
– Hold the central body with the front tip of the plate holder to avoid harm to the palatal mucosa.
– Place the distractor body so that the hole for the titanium safety wire is in a horizontally accessible position.
– If the palatal mucosa is very thick and covers the titanium safety wire holes of the distractor, place the titanium safety wires into the holes before the distractor body is placed into the footplates.
– When inserting the screw, rotate the screwdriver shaft using your fingertips. The screwdriver handle is not attached to the shaft. Once the blocking screw is properly engaged, the screwdriver handle may be mounted to the shaft to further tighten the blocking screw. Do not overtighten the blocking screw.
– Place gauze in the mouth to prevent ingestion in the event the blocking screw drops from the screwdriver blade.
– It is recommended to begin distraction 5-7 days after distractor placement.
– Carefully plan the rate and frequency of the distraction in order to avoid injuries to important neurovascular structures that may result from forces associated with the maxillary expansion.
– Do not distract with higher rates than 0.33 mm. This could be detrimental to the patient health and treatment outcome.
– Do not force the instrument after it comes to a stop. Its head may slip off the distractor central body causing damage to the soft tissue of the mouth.
– Do not activate the distractor central body in reverse during palatal distraction.
– During the first days of distraction, the distractor might need to be blocked with the blocking screw by the surgeon every day after expansion to prevent it from being activated unintentionally. The blocking screw must be removed each day prior to distraction.
– Press plate holder against the footplate while removing the threaded pin from the footplate socket to prevent extrusion of the bone screws.
– Hold the central body with the front tip of the plate holder to avoid harm to the palatal mucosa during rotation of the central body.
– Allow the bone to consolidate for 12 weeks. This time period may vary in relation to patient age and to accomplished palatal expansion and should be determined by clinical evaluation and radiographic or CT evidence of bone healing.
– Consolidation time should be lengthened to allow bone to mineralize and become strong enough to resist high forces from skull bones and stretched palatal soft tissue.
– The timing for distractor removal should be determined by clinical evaluation and radiographic or CT evidence of bone healing.
– The patient should be advised to report any unusual changes in the palatal region to the surgeon and be closely monitored if any asymmetric change occurs.

Patient's Care precautions:
– Accept the transpalatal distractor as a foreign body in your mouth.
– Should you have any nose-bleeding, missing or broken safety wires, redness, drainage, undue pain, questions or concerns, contact your physician immediately.
– Under instructions from your physician, you need to activate the distractor each day.
– Please follow the distractor activation steps within the patient care guide. Mark your progress on the distraction calender.
– Observe arrow direction when operating the distractor.
– Follow a soft diet during the entire distraction treatment.
– Maintain daily oral hygiene.
– Do not tamper with, remove or activate the distractor with the toothbrush, tongue, finger or any foreign object. Do not tamper with the safety wires.
– Consider gentle cleaning of the nose. Avoid aggressive nose blowing.
– Comply fully with your doctor's instructions. Regular follow-up visits are essential for long term clinical success.

General 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.

Warnings
– Do not activate the distractor before the osteotomies are made.
– Do not activate the distractor to its maximum width intraoperatively.
– At any time while the distractor is in the patient's mouth, both sides of the distractor must be secured to the teeth with the safety wires in order to avoid hazard of swallowing or choking.

MRI Information
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 (3 T) under MRI Conditions using RF Coils (whole body averaged specific absorption rate [SAR] of 2 W/kg for 15 minutes).

Non-clinical testing of worst case scenario in a 1.5T and 3T MRI system lead to temperature rises of 12.8 °C (1.5 T) and 11.7 °C (3 T) (whole body averaged specific absorption rate [SAR] of 2 W/kg for 15 minutes). Testing was conducted on a GE CVMR 1.5T MRI system and a GE MR750 3.0T MRI system.

Precautions:
The above mentioned test relies on non-clinical testing. The actual temperature rise in the patient will depend on a variety of factors beyond the SAR and time of RF application. Thus, it is recommended to pay particular attention to the following points:
– It is recommended to thoroughly monitor patients undergoing MR scanning for perceived temperature and/or pain sensations.
– Patients with impaired thermo regulation or temperature sensation should be excluded from MR scanning procedures.
– Generally it is recommended to use an MRI system with low field strength in the presence of conductive implants. The employed specific absorption rate (SAR) should be reduced as far as possible.
– Using the ventilation system may further contribute to reduce temperature increase in the body.

Treatment before device is used
Synthes products supplied in a non-sterile condition must be cleaned and steam-sterilized prior to surgical use. Prior to cleaning, remove all original packaging. Prior to steam-sterilization, place the product in an approved wrap or container. Follow the cleaning and sterilization instruction given by the Synthes brochure "Important Information".

Device-specific treatment instructions before surgical use:
Determine the post-distraction anatomical goal by conducting an evaluation of the craniofacial pathology through clinical exams, CT scan, frontal cephalogram and/or x-ray. Dental models are beneficial for selecting the appropriate distractor size, determining the location of the osteotomies and placement of the distractor footplates

Precautions:
Evaluate:
– The patient teeth to ensure that the distractor could be secured on both sides with safety wires.
– Desired vector of movement and the magnitude of the desired skeletal correction.
– Palatal mucosa thickness.
– Palatal bone thickness in the area of footplate placement. The bone should provide adequate strength to sustain forces during the treatment. Thin palatal bone in the sinuses areas should be avoided.
– Anatomic abnormalities of the distraction site (e.g. low maxillary sinuses) and bone quality; especially in young patients, cleft patients and patient's with edentulous maxillae.
– Necessary space for distractor placement and movement of the activation instrument during the entire course of treatment.
– Surgical access for osteotomy (e.g. proximity of the incisors).
– Patient cooperation with device activation process and oral hygiene.

Evaluate patient cooperation with device activation process and oral hygiene.

Explain the treatment process to the patient before surgery, including the osteotomies, the application and functionality of the transpalatal distractor and the time needed for the distraction and consolidation periods. Clearly inform the patient that a diastema between the incisors will occur; this will be corrected later by the orthodontic treatment.

Special operating instructions
Special operating instructions are found in the Transpalatal Distractor Surgical Technique 036.001.125.

Surgical Steps are described in the Surgical Technique as follow:

– Preoperative Planning

– Transpalatal Distractor Placement
  1. Perform osteotomies.
  2. Assemble transpalatal distractor.
  3. Fit transpalatal distractor.
  4. Make incisions for footplate placement.
  5. Fixate footplate to the bone.
  6. Place distractor body.
  7. Confirm activation of transpalatal distractor.
  8. Secure transpalatal distractor with titanium safety wires.
  9. Lock transpalatal distractor.

– Postoperative Considerations-Distraction Protocol
  1. Blocking Screw removal.
  2. Suggested distraction protocol.
  3. Document patient progress.
  4. Patient care.
  5. Optional: Exchange distractor body during distraction period.

– Consolidation Period.
– Transpalatal Distractor Removal.

Please refer to the Surgical Technique for detailed information on the surgical steps.

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

Processing of Transpalatal Distractor Bodies (04.509.005, 04.509.006, 04.509.007)
Processing instructions for Transpalatal Distractor Bodies (04.509.005, 04.509.006, 04.509.007) deviate from the general processing instructions for non-sterile implants. Specific instructions for the processing of these part numbers are listed below.

These recommendations are for processing non-sterile Synthes implants. The information provided applies to unused and unsoiled Synthes implants only. Explanted Synthes implants must never be reprocessed and should be handled according to hospital protocol upon removal. Any implant that has not been used, but has become soiled, should be handled according to hospital protocol. Do not reprocess soiled implants. These recommendations are to be followed unless otherwise noted on specific product inserts.

Cautions
– Any implant that has not been used, but has become soiled with blood, tissue and/or bodily fluids/matter, should be handled according to hospital protocol. Synthes does not recommend the reprocessing of soiled implants.
– Synthes implants should not be lubricated.
– Do not use a Synthes implant if the surface has been damaged.
– Do not use steel wool or abrasive cleaners on Synthes implants.
– Synthes implants should not be processed or transported with any type of soiled or contaminated materials.
– Synthes implants are critical devices and must be terminally sterilized prior to use.
– The sterilization parameters are only valid for devices that are adequately cleaned.
– Only rigid sterilization containers approved for moist heat sterilization may be used with Synthes devices and loaded cases (a case with all or part of its assigned contents).
– The parameters listed are only valid for properly installed, maintained, calibrated and compliant reprocessing equipment in accordance with ISO 15883 and ISO 17665.
– Cleaning agents with a pH 7–9.5 are recommended. Cleaning agents with a pH-value up to 11 and higher than 11 respectively should only be used considering the data regarding material compatibility according to its data sheet. Refer to Material Compatibility of Synthes Instruments and Implants in Clinical Reprocessing.
– The options in using rigid sterilization containers with Synthes devices and loaded cases are as follows:
– No more than one (1) fully loaded case can be placed directly into a rigid sterilization container.
– Instrument trays from no more than one (1) loaded case can be placed in the rigid sterilization container.
– Stand-alone modules/racks or single devices must be placed, without stacking, in a container basket to ensure optimal ventilation.
– Rigid sterilization container must have a maximum volume to vent ratio of no greater than 322 cm^3/cm^2.
– Only rigid sterilization containers approved for pre-vacuum steam sterilization can be used with Synthes devices and loaded cases.
– The following parameters are only valid for properly installed, maintained, calibrated and compliant reprocessing equipment.
– Consult national regulations and guidelines for additional information. Compliance is additionally required with internal hospital policies and procedures and recommendations of manufacturers of detergents, disinfectants, and any clinical processing equipment.

Limits on reprocessing
– Repeated processing cycles that include mechanical washing and sterilization have minimal effects on Synthes implants.
– Synthes implants should be inspected for corrosion, damage such as scratches and notches, debris, discoloration or residue.
– A discoloration has no adverse effect on titanium or titanium alloy implants. The protective oxide layer is fully maintained.
– Any implant with corrosion, scratches, notches, residue or debris should be discarded.

Point of Use Care
– Implants should remain covered until needed to avoid becoming soiled or contaminated. Only those to be implanted should be handled.
– Minimal handling of implants is necessary to prevent damage to the surface.

Containment and Transportation
– Implants should not come in contact with soiled devices and/or equipment.
– Avoid cross contamination of implants with soiled instruments during transport.

Preparation for Processing
– Synthes does not recommend the reprocessing of soiled implants.

Alternative manual precleaning method:
1. Remove debris
Rinse the device under running cold tap water for a minimum of 2 minutes. Use a sponge, soft lint-free cloth or soft-bristled brush to assist.
Precaution: Never immerse this implants in aqueous solutions or in an ultrasonic bath. Do not use pressurized water as this will cause damage to the system.
2. Manipulate moving parts
Manipulate all moving parts under running tap water.
3. Spray and wipe
Spray and wipe the device using a neutral pH enzymatic solution for a minimum of 2 minutes. Follow the enzymatic detergent manufacturer's directions for correct temperature, water quality (i.e. pH, hardness) and concentration/dilution.
4. Clean with detergent
Clean the device manually under running warm water using an enzymatic cleaner or detergent for a minimum of 5 minutes. Manipulate all moving parts under running water. Use a soft-bristled brush and/or soft lint-free cloth. Follow the enzymatic cleaner or detergent manufacturer's instructions for use for correct temperature, water quality and concentration/dilution.
5. Rinse with tap water
Rinse the device thoroughly using cool to lukewarm running water for a minimum of 2 minutes. Use a syringe or pipette to flush lumens and channels.
6. Visually inspect device
Inspect the cannulations, sliding sleeves, etc. for visible soil. Repeat steps 1–6 if visible residues.
7. Final rinse with de-ionized/purified water
Final rinse with de-ionized or purified water for a minimum of 2 minutes.
8. Dry
Dry device using a clean, soft lint-free cloth or clean compressed air.

Cleaning – Automated/Mechanical washer Method
Equipment: washer/disinfector, enzymatic cleaner or detergent solution

Use the following cycle parameters:

Cycle	Minimum Time (minutes)	Minimum Temperature/Water	Type of Detergent
Pre-wash	2	Cold tap water	N/A
Wash I	2	Cold tap water (< 40 °C)	Cleaning agent*
Wash II	5	Warm tap water (> 40 °C)	Cleaning agent*
Rinse	2	Warm DI or PURW (> 40 °C)	N/A
Thermal Disinfection	5	> 93 °C	N/A
Dry	40	> 90 °C	N/A

* see Additional Information

Thermal disinfection
– For automated/mechanical washer cleaning, thermally disinfect at a minimum of 93 °C for a minimum of 5 minutes.

Inspection
– Synthes implants should be inspected after processing, prior to sterilization.
– Any implant with corrosion, scratches, flaws, residue or debris should be discarded.

Packaging
Put cleaned, dry implants into the proper location in the Synthes case. Additionally, use an appropriate sterilization wrap or reusable rigid container system for sterilization, such as a sterile barrier system according to ISO 11607. Care should be taken to protect implants, and pointed and sharp instruments from contact with other objects that may damage the surface.

Sterilization
The following are the recommendations for the sterilization of Synthes implants:

Cycle Type	Minimum Sterilization Exposure Time (minutes)	Minimum Sterilization Exposure Temperature	Minimum Dry Time*
Prevacuum *Saturated steam-forced air removal (pre-vacuum) (minimum three pulses)*	4	132 °C	20 minutes
	3	134 °C	20 minutes

* When applying dry times to Synthes cases and their accessories, dry times outside the standard healthcare prevacuum parameters may be required. This is especially important for polymer-based (plastic) cases/trays used in conjunction with heavy duty nonwoven sterilization wraps. The current recommended dry times for Synthes cases can range from a standard 20 minutes to an extended time of 60 minutes. The dry time is most often influenced by the presence of polymer based (plastic) materials; therefore, changes such as elimination of silicone mats and/or change in sterile barrier system (e.g. heavy grade to light grade wrap or the use of rigid sterilization containers) can reduce the necessary dry time. Dry times may be highly variable due to differences in packaging materials (e.g. nonwoven wraps), environmental conditions, steam quality, implant materials, total mass, sterilizer performance and varying cool down time. The user should employ verifiable methods (e.g. visual inspections) to confirm adequate drying.

– The autoclave manufacturer's operating instructions and recommended guidelines for maximum sterilization load should be followed. The autoclave must be properly installed, maintained, and calibrated. Only legally marketed, sterilization barriers (e.g. wraps, pouches or containers) should be used by the enduser for packaging terminally sterilized devices.
– For product sold sterile, refer to device-specific insert for regarding resterilization.
– Rigid Sterilization Container Use Instructions and Considerations
  In order to ensure proper sterilization of Synthes implants when using a rigid sterilization container, the following must be taken into consideration:
  – The rigid sterilization container manufacturer's instructions for use are to be followed. If questions arise regarding the use of the rigid sterilization container, Synthes recommends contacting the manufacturer of that specific container for guidance.
  – The options in using rigid sterilization containers with Synthes devices and loaded cases are as follows:
    – No more than one (1) fully loaded case can be placed directly into a rigid sterilization container.
    – Instrument trays from no more than one (1) loaded case can be placed in the rigid sterilization container.
    – Stand-alone modules/racks or single devices must be placed, without stacking, in a container basket to ensure optimal ventilation.
– When selecting a rigid sterilization container for Synthes devices and loaded cases, the rigid sterilization container must have a maximum volume to vent ratio of no greater than 322 cm^3/cm^2. For any questions related to the volume to vent ratio, please contact the container manufacturer.
– Only rigid sterilization containers approved for pre-vacuum steam sterilization can be used with Synthes devices and loaded cases following the parameters provided in the table above.

Additional Information
– Synthes used the following supplies during validation of these reprocessing recommendations. These supplies are not listed in preference to other available supplies which may perform satisfactorily. Cleaning Agent Information: deconex TWIN PH10, deconex POWER ZYME, and deconex TWIN ZYME. Lint-free cloth: Berkshire Durx 670.
– The cleaning and sterilization information is provided in accordance with ANSI/AAMIST81, ISO 17664, AAMI TIR 12, ISO 17665-1 and AAMI ST77.
– The recommendations provided above have been validated by the medical device manufacturer as being capable of cleaning and sterilizing a non-sterile Synthes medical device implants prior to surgical use. It remains the responsibility of the processor to ensure that the processing is actually performed using equipment, materials and personnel in the reprocessing facility, and achieves the desired result. This requires validation and routine monitoring of the process. Likewise, any deviation by the processor from the recommendations provided should be properly evaluated for effectiveness and potential adverse consequences.

Manufacturer Contact
For further information, contact your local Synthes sales representative.

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