Important Information
(with Cleaning and Sterilization Instructions)

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DePuy Synthes
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Important Information

This Important Information document is to be used in conjunction with the corresponding product specific Instructions for Use (IFU), where applicable.

Basic Instructions on the Use of Synthes Implants and Instruments

Product Description
Surgical implants and instruments offer solutions for orthopedic surgeries of the human musculoskeletal system. They also play a generally supportive role in treatment, healing of fractures, and reconstructive surgery (osteosynthesis and correction of degenerative diseases). Implants are not intended to permanently replace body structures or bear the body's weight (see product-specific instructions).

Important considerations
Consider the following points when treating traumatic and/or degenerative skeletal changes:

1. Selecting the implant/system. It is important to select a suitable device. For implants make sure to select an appropriately sized and shaped product suitable for the intended application.
Infection may impact the surgery outcome. It's important to effectively manage the infection and decide the appropriate timing of the implantation procedure.
The characteristics of human bone and soft tissue pose restrictions on the size and strength of implants. No partial weight-bearing or non-weight-bearing product can be expected to withstand the full, unsupported weight of the body. The patient must restrict physical activities that would place inappropriate stress upon the implant or allow inappropriate movement at the fracture site and thus delay healing. The patient must be informed accordingly.

2. Patient-related factors. A series of patient-related factors may have a strong influence on the success of surgery:
a Weight. An overweight or obese patient can place so much stress on the product that it will fail, perhaps even reversing the effects of surgery.
b Occupation or activity. Professional occupations pose a risk when external forces subject the body to substantial physical loads. This can cause the product to fail and even undo the achievements of surgery.
c Senility, mental illness, or alcoholism. These conditions may cause the patient to ignore certain necessary limitations and precautions, leading to the failure of the product or other complications.
d Certain degenerative diseases and smoking. In some cases, a degenerative disease may be so advanced at the time of implantation that it may substantially decrease the expected useful life of the implant. In such cases, the products serve only as a means to delay or temporarily relieve the disease.
e Sensitivity to foreign bodies. Where hypersensitivity to a material is suspected, appropriate tests should be undertaken prior to selecting or implanting the material.

3. Correct handling. Correct handling of the implants and instruments is extremely important. If the shape of the implant must be altered, the device should not be bent sharply, bent backwards, notched, or scratched. Such manipulations, in addition to all other improper handling or use, can produce surface defects and/or concentrate stress in the core of the implant. This in turn may eventually cause the product to fail.

4. Postoperative care is essential. Patients must be informed about the implant's load restrictions, postoperative behavior and increasing physical loads. Failure to do this may result in malalignment, delayed bone healing, implant failure, infections, thrombophlebitis, and/or wound hematomas.

5. Removal of the osteosynthetic product. While the physician makes the final decision on when to remove the implant, it is advisable – if possible and appropriate for the individual patient – to remove fixation products after the healing process is complete. This holds true particularly for young and active patients.

6. Compatibility. Synthes ensures the compatibility of its different original implants and/or instruments according to their intended use. The product-specific instructions for use as described by Synthes must be followed. If not otherwise mentioned, it is not advisable to mix Synthes products with those of different manufacturers, since designs, materials, mechanics, and constructions are not harmonized. Synthes assumes no liability for any complications arising from mixing components or from using devices from other manufacturers.
If not otherwise mentioned it is not recommended to mix different implant metals. Mixing of metals may lead to galvanic corrosion and a release of ions. This may cause inflammatory response, metal sensitivity reactions, and/or long term detrimental systemic effects. In addition, the corrosion process can reduce the mechanical strength of the implant.

7. Information and qualification. Health Care Professionals should be fully aware of the intended use of the products and the applicable surgical techniques, and they should be qualified by appropriate training.

8. Potential Adverse Events, Undesirable Side Effects and Residual Risks:
- Implant failure from selecting the wrong implant and/or overloading the osteosynthesis
- Infection
- Soft Tissue Damage
- Allergic reactions from material incompatibility
- Delayed healing from vascular disturbances
- Pain triggered by the implant

The corresponding Instructions for Use detail specific potential adverse events, undesirable side effects and residual risks, if applicable.

9. MRI – Magnetic Resonance Imaging
When a device has been evaluated for use in the MR environment, MRI information is available in the Instructions for Use at www.depuysynthes.com/ifu and/or www.e-ifu.com.

Single-Use Products
Products intended for single use must not be re-used (see product-specific instructions and "Interpretation of symbols").
Re-use or clinical reprocessing may compromise the structural integrity of the device and/or lead to device failure. This may result in patient injury, illness or death. Furthermore, re-use 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.
Do not reprocess contaminated implants and single use instruments. Any Synthes implant and single use instrument 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 used and contaminated implants and single use instruments may appear undamaged, the implants and single use instruments may have small defects and internal stress patterns that may cause material fatigue.

Sterile Products
Products supplied in a sterile condition are labeled "STERILE" (see "Interpretation of symbols"). Remove products from the package in an aseptic manner. The manufacturer cannot ensure sterility if the package seal is broken, damaged or if the package is improperly opened, and assumes no liability in such instances.

Non-Sterile Products
Synthes products supplied in a non-sterile condition must be cleaned and steam sterilized prior to surgical use. Prior to cleaning, remove and dispose all original disposable packaging (e.g. silicone rubber guards, tip guards, protection caps, blisters, pouches, bags, packaging foam, card board etc.). Clean products before first and every use, and before returning for maintenance and repair. Prior to steam sterilization, place the product in an approved sterilization wrap or container.
The first and most important step in reprocessing all re-usable instruments is thorough (manual and/or mechanical) cleaning and rinsing. Thorough cleaning is a complex process whose success depends on various interrelated factors: Water quality, quantity and type of cleaning agent, cleaning method (manual, ultrasonic bath, washer/disinfector), thorough rinsing and drying, proper product preparation, time, temperature, and thoroughness of the individual responsible for cleaning.
Residual organic matter and/or a large number of microorganisms may reduce the effectiveness of the sterilization process.

Locating of the instrument or fragments of instruments
Synthes Instruments are designed and manufactured to perform safely within the scope of their intended use.
However, if a metallic instrument (e.g. steel, aluminum, titanium and its alloy etc.) breaks during use, a medical imaging device (e.g. CT, Radiation Devices etc.) can aid in locating fragments and/or components of the instrument.

Disposal of medical devices
If not otherwise mentioned, devices must be disposed of as a medical device in accordance with facility procedures.

Serious Incident
Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Reprocessing Synthes Reusable Devices – Instruments, Instrument Trays and Cases

These recommendations are for processing Synthes reusable devices. Synthes reusable devices include certain surgical instruments, instrument trays and cases. The information provided does not apply to Synthes implants. These recommendations are to be followed unless otherwise noted on specific product inserts.

Cautions	– All devices must be thoroughly cleaned and inspected prior to sterilization. Long, narrow lumens, blind holes, moving and intricate parts require particular attention during cleaning and inspection. During cleaning, only use cleaning agents that are labelled for use on medical devices and in accordance with the manufacturer's instructions (e.g. temperature, contact time, and rinse time). Cleaning agents with a used dilution pH of within 7–9.5 are recommended. Highly alkaline conditions (pH >11) can damage components/devices, such as aluminum materials. Do not use saline, environmental disinfection (including chlorine solutions) or surgical antiseptics (such as iodine- or chlorhexidine-containing products). Do not use a cleaning aid that can damage the surface of instruments such as steel wool, abrasive cleaners or wire brushes. – Only place Synthes devices with items of similar metallic composition together in an ultrasonic cleaner. – Soiled or used Synthes devices should not be loaded into a case for cleaning in a mechanical washer. Soiled Synthes devices must be processed separate from trays and cases. Synthes cases are designed to be an organizational tool for the steam sterilization process, a storage tool for all medical devices and an organizational tool for surgery. – The sterilization parameters are only valid for devices that are adequately cleaned. – The parameters listed are only valid for properly installed, maintained, calibrated and compliant reprocessing equipment in accordance with standards such as the ISO 15883 and ISO 17665 series. – Power Tool hand pieces and attachments should not be immersed in water or cleaning solution for clinical processing. Do not clean power equipment ultrasonically. Refer to product-specific literature for Power Tools. – Surgical patients identified as at-risk for Creutzfeldt-Jakob disease (CJD) and related infections should be treated with single-use instruments. Dispose of instruments used or suspected of use on a patient with CJD after surgery and/or follow current national recommendations. – Consult national regulations and guidelines for additional information. Compliance is additionally required with internal hospital policies and procedures and recommendations of manufacturers of cleaning agents and any clinical processing equipment.
Limits on reprocessing	– Repeated processing cycles as described in these instructions have minimal effects on Synthes surgical instrumentation. – End of life of a device is normally determined by wear and damage due to use. Evidence of damage and wear on a device may include but is not limited to corrosion (e.g. rust, pitting), discoloration, excessive scratches, flaking, wear and cracks. Improperly functioning devices, devices with unrecognizable markings, missing or removed (buffed off) part numbers, damaged and excessively worn devices should not be used. – Further details regarding end of life indicators are available from your sales representative or for download from the website: www.depuysynthes.com/ifu and/ or www.e-ifu.com. – Instruments can require testing prior to sterilization to ensure proper function. The method for the functional testing, when applicable for the instrument, is provided in the product specific instructions for use and using the functional control document available on www.depuysynthes.com/ifu and/ or www.e-ifu.com.
Point of Use Care	– Wipe blood and/or debris from device throughout surgical procedure to prevent it from drying onto the surface. – Flush cannulated devices with sterile or purified water to prevent the drying of soil and/or debris to the inside. – Soiled devices should be separated from non-contaminated devices to avoid contamination of personnel or surroundings. – Devices should be covered with a towel dampened with sterile or purified water to prevent blood and/or debris from drying.
Containment and Transportation	– Surgically used devices may be considered bio-hazardous and should be safely transported to a designated processing area in accordance with local policies.
Preparation for Cleaning (for all cleaning methods)	– It is recommended that devices should be reprocessed as soon as reasonably practical following use. – Disassemble device, if device is able to be disassembled, prior to reprocessing. Further detailed instrument dismantling instructions are available from your local sales representative or for download from the website: www.depuysynthes.com/ifu and/or www.e-ifu.com. – Open devices with ratchets, box locks or hinges. – Care should be taken in the handling and cleaning of sharp devices. These are recommended to be cleaned separately to reduce risks of injury. – Lumens/cannula of devices should be manually processed prior to cleaning. Lumens/cannula should first be cleared of debris. Lumens/cannula should be brushed thoroughly using appropriately sized soft-bristled brushes and twisting action. Brushes should be tight-fitting. Brush size should be approximately the same diameter of the lumen/cannulation to be cleaned. Using a brush that is too big or too small for the diameter of the lumen/cannulation may not effectively clean the surface of a lumen/cannulation. – Soak and/or rinse heavily soiled devices or cannulated devices prior to cleaning to loosen any dried soil or debris. Use a neutral or mild alkaline cleaning agent solution. Follow the cleaning agent manufacturer's instructions for use for correct exposure time, temperature, water quality and concentration. Use cold tap water to rinse devices. – Synthes devices must be cleaned separately from Synthes instrument trays and Synthes cases. Lids should be removed from cases for the cleaning process, if applicable.

Cleaning-Manual Method

1. Rinse soiled device under running cold tap water for a minimum of two minutes. Use a soft-bristled brush to assist in the removal of gross soil and debris.
2. Soak device in a neutral or mild alkaline cleaning agent solution for a minimum of ten minutes. Follow the cleaning agent manufacturer's instructions for use for correct exposure time, temperature, water quality and concentration.
3. Rinse device with cold water for a minimum of two minutes. Use a syringe, pipette, or water jet to flush lumens, channels and other hard to reach areas.
4. Manually clean device for a minimum of five minutes in a freshly prepared neutral or mild alkaline cleaning agent solution. Use a soft-bristled brush to remove soil and debris. Actuate joints, handles and other moveable device features to expose all areas to the cleaning agent solution, if applicable. Clean device under water to prevent aerosolization of contaminants. Note: fresh solution is a newly-made, clean solution.
5. Rinse device thoroughly using ambient (≤40 °C) tap water for a minimum of two minutes. Use a syringe, pipette or water jet to flush lumens and channels. Actuate joints, handles and other moveable device features in order to rinse thoroughly under running water, if applicable.
6. Visually inspect device. Repeat steps 2–6 until no visible soil remains on device.

Ultrasonic process: Pre-cleaning steps 1–6 should occur prior to this step

7. Prepare a fresh cleaning agent solution for the ultrasonic bath using a neutral or mild alkaline cleaning agent. Follow the cleaning agent manufacturer's instructions for use for correct exposure time, temperature, water quality and concentration. Note: fresh solution is a newly-made, clean solution.
8. Clean Synthes device ultrasonically for a minimum of 15 minutes, using a minimum frequency of 38 kHz.
9. Rinse device thoroughly with ambient (≤40 °C) deionized (DI) or purified (PURW) water for a minimum of two minutes. Use a syringe, pipette or water jet to flush lumens and channels. Actuate joints, handles and other moveable device features in order to rinse thoroughly under running water, if applicable.
10. Visually inspect device. Repeat steps 2–10 until no visible soil remains on device.
11. Perform a final rinse on device using ambient (≤40 °C) DI or PURW water for a minimum of 15 seconds.
12. Dry devices using a clean, soft, lint-free single-use cloth or medical grade compressed air. Ensure that all lumens and articulated areas are dried using compressed air.
13. Follow guidance in the disinfection section of this Important Information instructions for automated thermal disinfection, as manual disinfection is not recommended.

Cleaning-Disinfection Automated Method

1. Rinse soiled device under running cold tap water for a minimum of one minute. Remove gross soil using a soft-bristled brush or soft, lint-free cloth.
2. Manually clean device for a minimum of two minutes in a freshly prepared neutral or mild alkaline cleaning agent solution. Follow the cleaning agent manufacturer's instructions for the correct dilution, temperature, water quality and exposure time. Use a soft-bristled brush to remove soil and debris. Actuate joints, handles and other moveable device features to expose all areas to cleaning agent solution, if applicable. Clean device under water to prevent aerosolization of contaminants. Note: fresh solution is a newly-made, clean solution.
3. Rinse device using ambient (≤40 °C) running tap water for a minimum of one minute. Use a syringe, pipette or water jet to flush lumens and channels. Actuate joints, handles and other moveable device features in order to rinse thoroughly under running water, if applicable.
4. Prepare a fresh cleaning agent solution for the ultrasonic bath using a neutral or mild alkaline cleaning agent. Follow the cleaning agent manufacturer's instructions for the correct dilution, temperature, water quality and exposure time. Note: fresh solution is a newly-made, clean solution.
5. Clean Synthes devices ultrasonically for a minimum of 15 minutes, using a minimum frequency of 38 kHz.
6. Rinse device using ambient (≤40 °C) DI or PURW water for a minimum of two minutes. Use a syringe, pipette or water jet to flush lumens and channels. DI or PURW water must be used for final rinse.
7. Visually inspect device. Repeat steps 2–7 until no visible soil remains on device.
8. Automated washing shall be conducted in a validated washer-disinfector in compliance to ISO 15883-1 and -2, or to an equivalent standard. Load the device components in the washer-disinfector in accordance with manufacturer's instructions, ensuring that the devices and lumens can drain freely. Automated washing can be included as part of a validated washing, disinfection, and/or drying cycle in accordance to manufacturer's instructions. An example of a validated cycle used for cleaning validation included:

Cycle	Recirculation Time (minutes)	Water Quality/ Temperature	Type of Cleaning
Pre-wash	2	Cold tap water <40 °C	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	Critical water (RO, DI or distilled water) ≥93 °C	N/A
Dry	40	≥90 °C	N/A

* see section Additional Information

Thermal disinfection

For automated cleaning-disinfection, thermally disinfect at a minimum of 93 °C for a minimum of 5 minutes (see Cleaning-Disinfection Automated Method, including the water quality requirements). For devices with cannulations or lumens, orient the parts such that the lumen or cannulation are in a vertical position. If this is not possible due to space limitations within the automated/mechanical washer, use an irrigating rack/load carrier with connections designed to ensure an adequate flow of process fluids to the lumen or cannulation of the device if necessary.

Drying

If a dry cycle is not included in the mechanical washer:
– Dry each device thoroughly inside and out to prevent rusting and malfunction.
– Use a clean, soft, lint-free single-use cloth to avoid damage to the surface.

Pay special attention to threads, ratchets and hinges or areas where fluid can accumulate. Open and close devices so that all areas are reached. Dry hollow parts (lumens, cannulations) using the air jet with medical grade compressed air.

Inspection

Synthes instruments should be inspected after processing, prior to sterilization, for end of life indicators such as:
- Cleanliness, if any residual soil is discovered during inspection, repeat the cleaning steps on those devices until all visible soil is removed from the device.
- Lack of moisture, carefully inspect device lumens and moving parts. If moisture is detected, manual drying should be performed.
- Damage, including but not limited to corrosion (e.g. rust, pitting), discoloration, excessive scratches, flaking, cracks and wear.
- Proper function, including but not limited to sharpness of cutting tools, bending of flexible devices, movement of hinges/joints/box locks and moveable features such as handles, ratcheting and couplings. Damaged or worn devices should not be used.

Further detailed function control instructions and end of life indicators are available from your local sales representative or for download from the website at www.depuysynthes.com/ifu and/ or www.e-ifu.com.

Lubricate instruments with moving parts, such as hinges and joints, spring-loaded ball bearings, and threaded parts. It is recommended to lubricate and maintain Synthes instruments with Synthes Special Oil only.

Disassembled devices should be reassembled prior to sterilization unless otherwise noted or the case is not configured for the assembled device. Further detailed instrument dismantling instructions are available from your local sales representative or for download at www.depuysynthes.com/ifu and/ or www.e-ifu.com.

Packaging

Put cleaned, dry devices into the proper location in the Synthes case. Additionally, use an appropriate sterilization wrap (single or double wrap) or re-usable rigid container system for sterilization, such as a sterile barrier system according to ISO 11607 and wrapping techniques such as those described in ANSI/AAMI ST79. An example of a validated packaging material is the HALYARD® KIMGUARD® ONE-STEP® Wrap. Care should be taken to protect implants and pointed and sharp instruments from contact with other objects that may damage the surface.

Sterilization

Steam (moist heat) sterilization shall be performed in a locally approved, pre-vacuum (forced air removal) cycle. The steam sterilizer should be validated to the requirements of any local standards and guidance such as EN 285 or AAMI/ANSI ST8, including compliance to the requirements of ISO 17665. The steam sterilizer should be installed and maintained in compliance to manufacturer's instructions and local requirements. Ensure that a steam sterilizer cycle is chosen that is designed to remove air from porous or lumened device loads in accordance to manufacturer's instructions and does not exceed the maximal sterilizer load.

The following steam sterilization cycles are examples of validated cycles:

Cycle Type	Applicability	Sterilization Exposure Time (minutes)*	Sterilization Exposure Temperature*	Dry Time (minutes)**
Prevacuum Saturated steamforced air removal (pre-vacuum, three pulses)	USA	4	132 °C	20 to 60
	outside of USA	3	134 °C	20 to 60

* Extended steam exposure cycle can be used to meet local requirements (outside of USA) such as 134°C for 18 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 (i.e. heavy grade to light grade wrap) can reduce the necessary dry time. The user should employ verifiable methods (e.g. visual inspections) to confirm adequate drying. Dry times generally range from 20 to 60 minutes due to differences in packaging materials (Sterile Barrier System, e.g. wraps or re-usable rigid container systems), steam quality, device materials, total mass, sterilizer performance, and varying cool-down time. Do not exceed 140 °C during drying.

Storage

Packaged products should be stored in a dry, clean environment, protected from direct sunlight, pests, and extremes of temperature and humidity. Refer to sterilization wrap or rigid container manufacturers IFU for limits on sterile product storage time and storage requirements for temperature and humidity.

Additional Information

Further information regarding the use of specific cleaning agents, ultrasonic washers, washer-disinfector, packaging materials or sterilizers during validation studies are available on request. Synthes used the following during validation of these reprocessing recommendations:
- Manual cleaning: Manual Pre-Cleaning with Enzol® Enzymatic Detergent 8 mL/L at 16–17 °C, deconex® POWER ZYME 3 mL/L at 19–21 °C, Endozime® 6.24 g/L at 33–34 °C, and Ultrasonic Cleaning with Enzol® Enzymatic Detergent 8 mL/L at 18–25 °C.
- Automated Cleaning: Manual Pre-Cleaning with Enzol® Enzymatic Detergent 8 mL/L at 16–17 °C and Ultrasonic Cleaning with Enzol® Enzymatic Detergent 8 mL/L at 18–25 °C. Water-disinfector cleaning with (Wash 1) Prolystica® 2X Concentrate Enzymatic Cleaner 1 mL/L at 23–26 °C and (Wash 2) Prolystica® 2X Neutral Detergent 1 mL/L at 44–46 °C, NpH Klenz® 0.78 g/L at 41–42 °C, neodisher® MediZym 5 mL/L at 45 °C.
- Lint-Free Cloth: Berkshire Durx 670.
- Sterilization wrap: HALYARD® KIMGUARD® ONE-STEP polypropylene wrap KC600 (equivalent to 2 layers of CSR wrap).

The recommendations provided above have been validated by the medical device manufacturer as being capable of preparing a non-sterile Synthes medical device. These instructions for use have been verified and validated in accordance with ISO 17664, AAMI TIR 12, ANSI/AAMI/ISO 17665-1, ANSI/AAMI ST79 and ANSI/AAMI ST77. It remains the responsibility of the processor to ensure that the processing is 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.
The chemical quality of the water used during reprocessing can impact device safety. Facilities should use the recommended water quality requirements for device reprocessing in accordance with local guidance (such as AAMI TIR 34, Water for the reprocessing of medical devices) and these instructions for use.

Manufacturer Contact

For further information, contact your local Synthes sales representative.

Processing Non-sterile Synthes Implants and single use Instruments

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

Cautions

- Any implant or single use instrument 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 or single use instruments.
- Do not use a Synthes implant or single use instrument if the surface has been damaged.
- Synthes implants and single use instruments should not be processed or transported with any type of soiled or contaminated materials.
- All devices must be thoroughly cleaned and inspected prior to sterilization. Long, narrow lumens, blind holes, moving and intricate parts require attention during cleaning and inspection. During cleaning, only use cleaning agents that are labelled for use on medical devices and in accordance with the manufacturer's instructions. Cleaning agents with a used dilution pH of within 7–9.5 are recommended. Highly alkaline conditions (pH >11) can damage components/devices, such as aluminum materials. Do not use saline, environmental disinfection (including chlorine solutions) or surgical antiseptics (such as iodine- or chlorhexidine-containing products). Do not use a cleaning aid that can damage the surface of implants such as steel wool, abrasive cleaners or wire brushes. Refer to Material Compatibility of Synthes Instruments and Implants in Clinical Reprocessing.
- Synthes implants should not be lubricated.
- Synthes implants and single use instruments 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 standards such as the ISO 15883 and ISO 17665 series.

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.
- Consult national regulations and guidelines for additional information. Compliance is additionally required with internal hospital policies and procedures and recommendations of manufacturers of cleaning agents and any clinical processing equipment.

Limits on reprocessing

- Repeated processing cycles as described in these instructions have minimal effects on Synthes implants and single use instruments.
- Synthes implants or single-use intruments can require testing prior to sterilization to ensure proper function. The method for the functional testing, when applicable for the implant or instrument, is provided in the product specific instructions for use and using the functional control document available on www.depuysynthes.com/ifu and/ or www.e-ifu.com.
- Synthes implants and single use instruments 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 or single use instrument with corrosion, scratches, notches, residue or debris should be discarded.

Point of Use Care

- Implants and single use instruments should remain covered until needed to avoid becoming soiled or contaminated. Only those to be implanted or used should be handled.
- Minimal handling of implants is necessary to prevent damage to the surface.

Containment and Transportation

- Implants and single use instruments should not come in contact with soiled devices and/or equipment.
- Avoid cross contamination of implants and single use instruments with soiled instruments during transport.

Preparation for Processing

Synthes does not recommend the reprocessing of soiled implants or single use instruments.

Cleaning-Manual Method

1. Rinse device under running cold tap water for a minimum of two minutes. Use a soft-bristled brush to clean the device.
2. Soak device in a neutral or mild alkaline cleaning agent solution for a minimum of ten minutes. Follow the cleaning agent manufacturer's instructions for the correct dilution, temperature, water quality and exposure time.
3. Rinse device with cold water for a minimum of two minutes. Use a syringe, pipette or water jet to flush lumens, channels and other hard to reach areas.
4. Immerse the devices fully in the cleaning agent solution, ensuring that all lumens, or moving parts are flushed to ensure contact. Manually clean devices for a minimum of five minutes in a freshly prepared neutral or mild alkaline cleaning agent solution using a soft-bristled brush. Clean devices under water to prevent aerosolization of contaminants. Note: freshly prepared solution is a newly made, clean solution.
5. Rinse device thoroughly using ambient (≤ 40 °C) tap water for a minimum of two minutes. Use a syringe, pipette or water jet to flush lumen and channels.
6. Prepare a fresh cleaning agent solution for the ultrasonic bath using a neutral or mild alkaline cleaning agent. Follow the cleaning agent manufacturer's instructions for the correct dilution, temperature, water quality and exposure time. Note: a fresh solution is a newly-made, clean solution.
7. Clean Synthes devices ultrasonically for a minimum of 15 minutes and a bath frequency of minimum 38 kHz.
8. Rinse device using ambient (≤40 °C) DI or PURW water for a minimum of two minutes. Actuate joints, handles and other moveable device features to rinse thoroughly, if applicable. Ensure all lumens are flushed. DI or PURW water must be used for final rinse.
9. Dry devices using a clean, soft, lint-free single-use cloth or medical grade compressed air. Ensure that all lumens and articulated areas are dried using compressed air.
10. Follow guidance in the disinfection section of this Important Information instructions for automated thermal disinfection, as manual disinfection is not recommended.

Cleaning-Disinfection Automated Method

1. Rinse devices under running cold tap water for a minimum of one minute. Use a soft-bristled brush or soft lint-free cloth to clean the device.
2. Prepare a fresh cleaning agent solution for the ultrasonic bath using a neutral or mild alkaline cleaning agent. Follow the cleaning agent manufacturer's instructions for the correct dilution, temperature, water quality and exposure time. Note: fresh solution is a newly-made, clean solution.
3. Immerse the devices fully in the cleaning agent solution, ensuring that all lumens, or moving parts are flushed to ensure contact. Clean Synthes devices ultrasonically for a minimum of 15 minutes, using a minimum frequency of 38 kHz.
4. Rinse device using ambient (≤40 °C) DI or PURW water for a minimum of two minutes. Use a syringe, pipette or water jet to flush lumens and channels. DI or PURW water must be used for final rinse.
5. Visually inspect device. Repeat steps 2–5 until devices are visibly clean.
6. Automated washing shall be conducted in a validated washer-disinfector in compliance to ISO 15883-1 and -2, or to an equivalent standard. Load the device components in the washer-disinfector in accordance with manufacturer's instructions, ensuring that the devices and lumens can drain freely. Automated washing can be included as part of a validated washing, disinfection, and/or drying cycle in accordance to manufacturer's instructions. An example of a validated cycle used for cleaning validation included:

Cycle	Recirculation Time (minutes)	Water Quality/ Temperature	Type of Cleaning
Pre-wash	2	Cold tap water <40 °C	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	Critical water (RO, DI or distilled water) ≥93 °C	N/A
Dry	40	≥90 °C	N/A

* see section Additional Information

Thermal disinfection

For automated cleaning-disinfection, thermally disinfect at a minimum of 93 °C for a minimum of 5 minutes (see Cleaning-Disinfection Automated Method, including the water quality requirements). For devices with cannulations or lumens, orient the parts such that the lumen or cannulation are in a vertical position. If this is not possible due to space limitations within the automated/mechanical washer, use an irrigating rack/load carrier with connections designed to ensure an adequate flow of process fluids to the lumen or cannulation of the device if necessary.

Inspection

Synthes implants and single use instruments should be visually inspected in a clean environment under good lighting, after processing, prior to sterilization to verify that the devices do not have visible soil, damage or moisture.

Inspect devices for:
- Lack of moisture, carefully inspect device lumens and moving parts. If moisture is detected, manual drying should be performed.
- Cleanliness, if any residual soil is discovered during inspection, repeat the cleaning steps on those devices until all visible soil is removed from the device.
- Damage, including but not limited to corrosion (e.g. rust, pitting), discoloration, scratches, flaking, cracks and wear.
- Proper function, including but not limited to sharpness of cutting features, bending of flexible devices, movement of hinges/joints/box locks and moveable features such as ratcheting and couplings and missing or removed part numbers.

Improperly functioning devices, devices with unrecognizable markings, missing or removed (buffed off) part numbers, damaged and worn devices should be discarded.

Packaging

Put cleaned, dry implants or single use instruments into the proper location in the Synthes case. Additionally, use an appropriate sterilization wrap (single or double wrap) or re-usable rigid container system for sterilization, such as a sterile barrier system according to ISO 11607 and wrapping techniques such as those described in ANSI/AAMI ST79. An example of a validated packaging material is the HALYARD® KIMGUARD® ONE-STEP® Wrap. Care should be taken to protect implants and pointed and sharp instruments from contact with other objects that may damage the surface.

Sterilization

Steam (moist heat) sterilization shall be performed in a locally approved, pre-vacuum (forced air removal) cycle. The steam sterilizer should be validated to the requirements of any local standards and guidance such as EN 285 or AAMI/ANSI ST8, including compliance to the requirements of ISO 17665. The steam sterilizer should be installed and maintained in compliance to manufacturer's instructions and local requirements. Ensure that a steam sterilizer cycle is chosen that is designed to remove air from porous or lumened device loads in accordance to manufacturer's instructions and does not exceed the maximal sterilizer load.

The following steam sterilization cycles are examples of validated cycles:

Cycle Type	Applicability	Sterilization Exposure Time (minutes)*	Sterilization Exposure Temperature*	Dry Time (minutes)**
Prevacuum Saturated steamforced air removal (pre-vacuum, three pulses)	USA	4	132 °C	20 to 60
	outside of USA	3	134 °C	20 to 60

* Extended steam exposure cycle can be used to meet local requirements (outside of USA) such as 134°C for 18 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 (i.e. heavy grade to light grade wrap) 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, device materials, total mass, sterilizer performance and varying cool-down time. The user should employ verifiable methods (e.g. visual inspections) to confirm adequate drying. Do not exceed 140 °C during drying.

– For product sold sterile, refer to device-specific insert regarding re-sterilization.
– Rigid Sterilization Container Use Instructions and Considerations

In order to ensure proper sterilization of Synthes implants and single use instruments 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.

Storage

Packaged products should be stored in a dry, clean environment, protected from direct sunlight, pests, and extremes of temperature and humidity. Refer to sterilization wrap or rigid container manufacturers IFU for limits on sterile product storage time and storage requirements for temperature and humidity.

Additional Information

Further information regarding the use of specific cleaning agents, ultrasonic washers, washer-disinfector, packaging materials or sterilizers during validation studies are available on request. Synthes used the following during validation of these reprocessing recommendations:
– Manual cleaning: Manual Pre-Cleaning with Prolystica® 2X Concentrate Enzymatic Cleaner 1 mL/L at 14–16 °C, deconex® POWER ZYME 3 mL/L at 19–21 °C, Endozime® 6.24 g/L at 33–34 °C, and Ultrasonic Cleaning with Prolystica® 2X Concentrate Enzymatic Cleaner 1 mL/L at 12–21 °C.
– Automated Cleaning: Manual Pre-Cleaning with Prolystica® 2X Concentrate Enzymatic Cleaner 1 mL/L at 14–16 °C, NpH Klenz® 0.78 g/L at 41–42 °C, neodisher® MediZym 5 mL/L at 45 °C. Water-disinfector cleaning with (Wash 1) Prolystica® 2X Concentrate Enzymatic Cleaner 1 mL/L at 23–26 °C and (Wash 2) Prolystica® 2X Neutral Detergent 1 mL/L at 44–46 °C.
– Lint-Free Cloth: Berkshire Durx 670.
– Sterilization wrap: HALYARD® KIMGUARD® ONE-STEP polypropylene wrap KC600 (equivalent to 2 layers of CSR wrap).

The recommendations provided above have been validated by the medical device manufacturer as being capable of preparing a non-sterile Synthes medical device. These instructions for use have been verified and validated in accordance with ISO 17664, AAMI TIR 12, ANSI/AAMI/ISO 17665-1, ANSI/AAMI ST79 and ANSI/AAMI ST77. It remains the responsibility of the processor to ensure that the processing is 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.

The chemical quality of the water used during reprocessing can impact device safety. Facilities should use the recommended water quality requirements for device reprocessing in accordance with local guidance (such as AAMI TIR 34, Water for the reprocessing).

Manufacturer Contact

For further information, contact your local Synthes sales representative.

Material Compatibility of Synthes Instruments and Implants in Clinical Processing

Knowledge of the materials used and their properties is essential for ensuring that instruments are proficiently processed and maintained.

Stainless steels
Synthes instruments are made predominantly from corrosion-resistant steels, recognizable by their shiny or dull metallic color. As a result of their high chromium and nickel content, corrosion-resistant steels form a protective chromium oxide layer, known as a passive layer, on the metal surface. This passive layer protects the instrument against corrosion and rust. Incorrect or careless handling (e.g. damage to the surface) and attacks of a chemical, electrochemical or physical nature, can adversely affect the corrosion resistance.
Two types of stainless steels are used, differentiated based on their composition and properties:
- Martensitic steels, which are corrosion resistant and whose high hardness can be influenced and adjusted by heat treatment, possess high wear resistance and high cutting edge retention. These steels are used for cutting and sharp-pointed instruments, e.g. drill bits, reamer heads, awl, burrs or cutting edges of pliers.
- Austenitic steels, which cannot be hardened by heat treatment, possess high corrosion resistance, elasticity and toughness, and are generally non-magnetic. These steels are used for non-cutting instruments, e.g. drill guides, gauges and aiming devices.
- Synthes recommends disinfectants, cleaners or detergents with pH 7–11 for all stainless steels.

Aluminum, titanium and its alloys
Since aluminum is a lightweight material it is used, for example, for the graphic cases, instrument handles and certain other instrument parts. An electrochemical surface treatment (anodizing, "Ematal" or hard anodizing) produces a resistant oxide layer on the aluminum, which can be dyed.
Titanium and titanium alloys are widely used as implant materials. On instruments titanium is used for only a few applications, mainly color coding of instruments. The surface of titanium alloys is also treated electrochemically (anodizing), producing a resistant oxide layer. Various color shades can be applied using this layer.
Although anodized aluminum, titanium and its alloys have good corrosion resistance, contact with strong alkaline detergents or disinfectants and solutions containing iodine or certain metal salts can lead to chemical attack and dissolution of the surface depending on the specific composition of the detergent.
Consequently, Synthes recommends disinfectants, cleaners or detergents with pH 6–9.5. Products with a higher pH value, especially higher than pH 11, should only be used subject to the material compatibility requirements stated on the data sheet and other information from the manufacturer of the detergent.

Plastics
Various plastics are used for certain instrument parts, e.g. handles, radiolucent parts. In addition to pure plastics composite materials are also used in some cases, e.g. wood-looking phenolic resin reinforced with fabric for handles of screwdrivers, raspatories, chisels, etc, or carbon-fiber reinforced plastics for aiming arms. All used plastics are able to withstand correct processing. Some of the plastics can become soft during steam sterilization, but do not undergo permanent deformation at normal sterilization temperatures below 140 °C. The material can, however, be damaged, for example by repeated immersion in disinfectants outside the pH range of 4–9.5 and by overstressing. Also, some rinsing aids can lead to discoloration or embrittlement of plastics and composites by repeated use.

Recommended Temperatures and pH Levels

Material	Temperature*	pH
Stainless steel	up to 149 °C	7–11
Aluminum	up to 150 °C	6–9.5
Titanium alloys	up to 150 °C	6–9.5
Plastics	up to 140 °C	4–9.5
Nitinol	up to 149°C	6–9.5

* The recommended processing temperatures take into account material properties and internally validated parameters for processing.

Causes of Corrosion and Surface Change or Damage
The surface of the instruments can be attacked and damaged by incorrect handling or contact with various substances. Awareness of the following possible causes of corrosion and material damage can help to avoid their occurrence.

Blood, pus, secretions etc.
Most human body fluids and residues contain chlorine ions, which can lead to corrosion if left to adhere to, or dry on, the instrument for prolonged periods. Instruments should therefore be cleaned and dried immediately after every use.

Saline solutions, iodine tinctures, water
The chlorine and iodine ions in these solutions cause pitting corrosion. Keep any contact with these ions to a minimum. Rinse instruments thoroughly with distilled water* to remove all residues.
Normal tap water often also contains chlorides, as well as high concentrations of other minerals, which can form marks with sharply defined edges on the instrument surface. These can usually be removed with distilled water* and non-abrasive stainless steel cleaners. Never leave instruments wet for long periods; always dry them immediately. Condensation moisture produced during sterilization can be avoided by prolonging the drying phase.

* A conductivity of < 0.5 µS is recommended for distilled water.

Detergents, disinfectants, rinsing aids and other additives
Excessive concentrations of these products or strongly acidic or alkaline detergents can attack the protective oxide layer of stainless steel, titanium and aluminum and lead to corrosion, discoloration or other changes of the materials, properties and surface conditions. When using such products, always follow the manufacturer's recommendations in respect of concentrations, contact times, temperatures and material compatibility. Products with pH levels between 7 and 9.5 are recommended. During repeated and prolonged use some rinsing aids can attack certain plastics and lead to discoloration or embrittlement. If the instruments are cleaned in an automated washer-disinfector, follow the directions of the manufacturers of the washer-disinfector, detergents, rinsing aids and other additives.

Steel wool, steel brushes, files and other abrasive cleaning tools
Never use extra fine or normal steel wool, steel brushes, files or other cleaning tools with abrasive effect on metals to clean surgical instruments, as this will result in mechanical damage to the passive layer, leading to corrosion and malfunction.

Contact between instruments made from different metals
If stainless steel instruments are left in contact for long periods with surface-damaged instruments and are simultaneously moistened with an electrolyte, rust can form at the points of contact. Steam, water, ultrasonic cleaning solutions or other liquids and solutions can act as electrolytes. Such phenomena are occasionally observed during automated cleaning. Corrosion products that have already formed can also be transferred to other instruments by electrolytes, thereby producing surface rust. If possible, instruments made from differing materials should be cleaned and sterilized separately. Consequently, instruments with corrosion or rust spots must always be excluded and exchanged for unblemished ones. Instruments should be cleaned in their opened and dismantled state in order to avoid not only insufficient cleaning but also crevice and fretting corrosion. The passive layer in crevices or joint gaps can be damaged by chemical or mechanical action, leading to corrosion.

Inadequate lubrication
Moving instrument parts, e.g. joints, sliding parts, dismantlable threaded connections etc. must be regularly lubricated. Constant metallic abrasion increases the damage to the passive layer and thus greatly increases the risk of corrosion. Synthes implants should not be lubricated.

Detergent residues in packing cloths
Cloths used to pack the devices for sterilization must be free of detergent or other residues. Such residues can be transferred to the device surface via steam and can interact with the surface.

Overstressing of instruments
Instruments are designed only for a specific purpose and must be used accordingly. Inappropriate use can lead to mechanical overstressing, malfunction and permanent instrument damage, and this in turn increases their susceptibility to corrosion.

Note on latex
Because Synthes instruments do not contain any latex, they can safely be used for patients with a latex allergy.

Note on Synthes Special Oil
Synthes Special Oil is a synthetic oil and non-toxic. It is recommended to lubricate and maintain Synthes instruments only with Synthes Special Oil.

Repair of Synthes instruments and ordering of spare parts

Defective instruments can be sent to your local Synthes customer service for repair. Customer service will assess whether the instrument can be repaired. Make sure that you enclose a delivery note with the defective instrument containing the following information:
- Hospital address, contact person and telephone number
- Article number of the defective instrument being returned
- Description of the problem

If you send in power tools for repair, loan machines can be made available (if in stock), allowing you to continue performing operations. Consult your local customer service for information on the availability of loan machines.
Your local customer service can deliver spare parts for defective or missing components of simple, multi-part instruments (e.g. depth gauges, drill sleeves). Consult your local customer service for information on the availability of spare parts.

Hazardous Substance identifier

Information of articles whose label indicates the presence of a Hazardous Substance (greater than 0.1% weight by weight) is provided here. Numbers listed below the symbol on the label indicate the presence of materials listed in the table below. Multiple numbers indicate more than one hazardous substance is present.

 #	**Material Present**	**Residual Risk**
 1	Cobalt CAS No. 7440-48-4 EC No. 231-158-0	This device or one or more components of this device contains the following substance defined as **CMR 1B** in a concentration above 0.1% weight by weight. Current scientific evidence supports that medical devices manufactured from cobalt do not cause an increased risk of cancer or adverse reproductive effects.
 2	Dibutyltin Dilaurate CAS No. 77-58-7 EC No. 201-039-8	This device or one or more components of this device contains the following substance defined as **CMR 1B** in a concentration above 0.1% weight by weight. Refer to ECHA website for more information. https://echa.europa.eu.

Interpretation of symbols

REF

Reference number

LOT

Lot or batch number

SN

Serial number

Manufacturer

EC REP

Authorized representative

2008-12

Manufacturing date

2008-12

Expiration date

Non-Sterile

STERILE

Sterile

CE

European Conformity

STERILE EO

Sterilized using ethylene oxide

Caution, see instructions for use

STERILE R

Sterilized using irradiation

Temperature indicator

Do not re-use

Temperature limitation

Do not re-sterilize

Lower limit of temperature

Do not use when packaging is damaged

Upper limit of temperature

Contains or presence of natural rubber latex

Keep away from sunlight

	SSt	TiCP
Material	Stainless steel	Pure titanium

0123

Notified body

	TAN (Ti6Al7Nb)
Material	Titanium-aluminum-niobium alloy

	TAV (Ti6Al4V)
Material	Titanium-aluminum-vanadium alloy

Consult instruction for use

Sterilization indicator

Keep dry

MR Conditional

MR unsafe

Medical Device

Material

Double Sterile Barrier System

Packaging Content

Contains Hazardous Substance

Single Patient Multiple Use

Single Sterile Barrier System

Contains a Medicinal Substance

CE
0123

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