Processing Synthes Reusable Medical Devices – Instruments, Instrument Trays and Cases

These recommendations are for processing Synthes reusable medical devices sold in North America. Synthes reusable medical 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	• Do not use steel wool or abrasive cleaners. • Avoid solutions containing iodine or high chlorine content. • Soiled or used Synthes devices should not be loaded in a case and cleaned in a mechanical washer. Synthes devices must be cleaned separately from Synthes instrument trays and Synthes cases. Soiled devices are devices that have blood, tissue and/or bodily fluid/matter in or on the surface of the devices. • Long, narrow cannulations, blind holes and intricate parts require particular attention during cleaning. • **All devices must be thoroughly cleaned.** • Synthes instruments are critical devices and must be terminally sterilized prior to use. • The sterilization parameters are only valid for devices that are adequately cleaned. • Do not stack trays of instruments in a mechanical washer. • See Sterilization section for Immediate-Use Steam Sterilization instructions. **Immediate-Use Steam Sterilization is only intended for individual instruments.** Synthes does not support or recommend sterilizing loaded cases or implants using this method. • The following parameters are only valid for properly installed, maintained, calibrated and compliant reprocessing equipment. • Cleaning agents with a pH within 7 – 9 are recommended. • The recommended cleaning method for Power tools is manual. Do not place Power tools in an ultrasonic cleaner. Do not submerge Power tools in aqueous solutions. Refer to product specific literature for care of Power tools. • The sterilization parameters **cannot be used for the Synthes Power Drive Unit, PN: 530.100, Power Drive Set, PN: 105.957, Synthes Piezoelectric Handpiece, PN: 05.001.401 and the Synthes Piezoelectric System, PN: 68.001.400.** For the Synthes Power Drive Unit and Power Drive Unit Set, the Synthes Piezoelectric Handpiece and Piezoelectric System, please refer to the User Manuals for Sterilization guidelines. • 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.
Limits on reprocessing	• Repeated processing cycles that include ultrasonic, mechanical washing and sterilization 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 (i.e. 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.

Clinical Processing Instructions

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	Soiled devices should be transported separate from non-contaminated devices to avoid contamination.

Preparation for Decontamination	• It is recommended that devices should be reprocessed as soon as is reasonably practical following use. • Disassemble device, if device is able to be disassembled, prior to cleaning. Refer to technique guide or other supplemental information for specific device disassembly and/or reassembly instructions. • Open devices with ratchets, box locks or hinges. • Remove sharp devices for manual cleaning or place into a separate tray. • 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. After brushing lumens/cannula, blow clean compressed air through lumen/cannulation to clear debris, if necessary. • Soak and/or rinse heavily soiled devices or cannulated devices prior to cleaning to loosen any dried soil or debris. Use a neutral pH enzymatic soak or detergent to soak devices. Follow the enzymatic cleaner or detergent 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	Equipment: various sized soft-bristled brushes, lint-free cloths, syringes, pipettes and/or water jet, neutral enzymatic cleaner or neutral detergent with a pH between 7 and 9. 1. Disassemble device, if device is able to be disassembled, prior to cleaning. Refer to technique guide or other supplemental information for specific device disassembly and/or reassembly instructions. 2. 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. 3. Soak device in a neutral pH enzymatic cleaner or detergent solution for a minimum of ten minutes. Follow the enzymatic cleaner or detergent manufacturer's instructions for use for correct exposure time, temperature, water quality and concentration. 4. 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. 5. Manually clean device for a minimum of five minutes in a freshly prepared neutral pH enzymatic cleaner or detergent solution. Use a soft-bristled brush to remove soil and debris. Actuate joints, handles and other movable device features to expose all areas to the detergent solution, if applicable. Clean device under water to prevent aerosolization of contaminants. *Note: fresh solution is a newly- made, clean solution.* 6. Rinse device thoroughly with 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. 7. Visually inspect device. Repeat the manual cleaning procedure (steps 2- 6) until no visible soil remains on device. 8. Perform a final rinse on device using DI or PURW water. 9. Dry device using a clean, soft, lint-free cloth or clean compressed air.

Cleaning – Mechanical Method: Ultrasonic	Equipment: ultrasonic cleaner, various sized soft-bristled brushes, lint-free cloths, syringes, pipettes and/or water jet, neutral enzymatic cleaner or neutral detergent with a pH between 7 and 9. Pre-clean method (Pre-clean method must be performed prior to ultrasonic mechanical method listed below.) 1. Disassemble device, if device is able to be disassembled, prior to cleaning. Refer to technique guide or other supplemental information for specific device disassembly and/or reassembly instructions. 2. 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. 3. Soak device in a neutral pH enzymatic cleaner or detergent solution for a minimum of ten minutes. Follow the enzymatic cleaner or detergent manufacturer's instructions for use for correct exposure time, temperature, water quality and concentration. 4. 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. 5. Manually clean device for a minimum of five minutes in a freshly prepared neutral pH enzymatic cleaner or detergent solution. Use a soft-bristled brush to remove soil and debris. Actuate joints, handles and other movable device features to expose all areas to the detergent solution, if applicable. Clean device under water to prevent aerosolization of contaminants. *Note: fresh solution is a newly- made, clean solution.* 6. Rinse device thoroughly using cold or warm 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. 7. Visually inspect device. Repeat steps 2- 6 until no visible soil remains on device. Ultrasonic process: (Pre-cleaning steps 1 -7 should occur prior to this step.) 8. Prepare a fresh detergent solution using a neutral pH enzymatic cleaner or detergent. Follow the enzymatic cleaner or detergent manufacturer's instructions for use for correct exposure time, temperature, water quality and concentration. *Note: fresh solution is a newly- made, clean solution*. 9. Clean Synthes device ultrasonically for a minimum of 15 minutes, using a minimum frequency of 40 KHz. 10. Rinse device thoroughly with 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. 11. Visually inspect device. Repeat steps 2- 10 until no visible soil remains on device. 12. Perform a final rinse on device using DI or PURW water for a minimum of 15 seconds. 13. Dry device using a clean, soft, lint-free cloth or clean compressed air.

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<td>Cleaning -- Mechanical Method: Mechanical washer</td>
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Equipment: Ultrasonic cleaner, washer/disinfector, various sized soft-bristled brushes, lint-free cloths, syringes, pipettes and/or water jet, neutral enzymatic cleaner or neutral detergent with a pH between 7 and 9. Note: Ultrasonic cleaning may cause further damage to devices that have prior surface damage.

Pre-clean method (Pre-clean method must be performed prior to mechanical washer method listed below.)
1. Disassemble device, if device is able to be disassembled, prior to cleaning. Refer to technique guide or other supplemental information for specific device disassembly and/or reassembly instructions.
2. 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.
3. Manually clean device for a minimum of two minutes in a freshly prepared neutral pH enzymatic or detergent solution. Follow the enzymatic cleaner or detergent 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 movable device features to expose all areas to detergent solution, if applicable. Clean device under water to prevent aerosolization of contaminants. Note: fresh solution is a newly- made, clean solution.
4. Rinse device using cold to lukewarm 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.
5. Prepare a fresh detergent solution using a neutral pH enzymatic cleaner or detergent. Follow the enzymatic cleaner or detergent manufacturer's instructions for the correct dilution, temperature, water quality and exposure time. Note: fresh solution is a newly- made, clean solution.
6. Clean Synthes devices ultrasonically for a minimum of 15 minutes, using a minimum frequency of 40 KHz.
7. Rinse device using 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.
8. Visually inspect device. Repeat steps 2 - 7 until no visible soil remains on device.

Mechanical Washer process: (Pre-cleaning steps 1 -8 should occur prior to this step.)

9. Process device using the following cycle parameters:
<table>
<tr><th>Cycle</th><th>Minimum Time (minutes)</th><th>Minimum Temperature/Water</th><th>Type of Detergent</th></tr>
<tr><td>Pre-wash</td><td>2</td><td>Cold tap water</td><td>N/A</td></tr>
<tr><td>Wash I</td><td>2</td><td>Cold to warm tap water</td><td>Neutral enzymatic pH between 7 and 9</td></tr>
<tr><td>Wash II</td><td>5</td><td>Warm tap water (>40°C)</td><td>Detergent with pH between 7 and 9</td></tr>
<tr><td>Rinse</td><td>2</td><td>Warm DI or PURW (>40°C)</td><td>N/A</td></tr>
<tr><td>Dry</td><td>40</td><td>90°C</td><td>N/A</td></tr>
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<td>Thermal disinfection</td>
<td>For automated cleaning, thermal disinfect at 93°C for a minimum of 2 minutes and 30 seconds. For devices with cannula or lumens, orient the part such that the lumen or cannulation is 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.</td>
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<td>Drying</td>
<td>If a dry cycle is not included in the mechanical washer or if the device is not processed in a mechanical washer:
• Dry each device thoroughly inside and out to prevent rusting and malfunction.
• Use a clean, soft, lint-free 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 using an air jet with clean compressed air.</td>
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<td>Inspection</td>
<td>• Synthes instruments should be inspected after processing, prior to sterilization, for:
  ◦ Cleanliness
  ◦ Damage, including but not limited to, corrosion (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 and
  ◦ Missing or removed (buffed off) part numbers
• Improperly functioning devices, devices with unrecognizable markings, missing or removed (buffed off) part numbers, damaged and worn devices should not be used.
• Disassembled devices should be reassembled prior to sterilization unless otherwise noted.</td>
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<td>Packaging</td>
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Only legally marketed, FDA-cleared sterilization barriers (e.g. wraps, pouches or containers) should be used by the end-user for packaging terminally sterilized devices.
<u>Rigid Sterilization Container Use Instructions and Considerations</u>
In order to ensure proper sterilization of Synthes' devices when using a rigid sterilization container, the following must be taken into consideration:

Only FDA-cleared rigid sterilization containers may be used with Synthes' devices and loaded graphic cases (a graphic case with all or part of its assigned contents).
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 graphic cases are as follows:

No more than one (1) fully loaded graphic case can be placed directly into a rigid sterilization container.
Instrument trays from no more than <u>one (1)</u> loaded graphic 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.

<u>Rigid sterilization container must have a maximum volume to vent ratio of no greater than 127in^3/in^2.</u> <u>For any questions related to the volume to vent ratio, please contact the container manufacturer.</u>
Only rigid sterilization containers approved for <u>pre-vacuum</u> steam sterilization can be used with Synthes' devices and loaded graphic cases following the sterilization parameters provided by Synthes.
End-users should follow ANSI/AAMI ST79 for additional information concerning the use of rigid sterilization containers.

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<td>Sterilization</td>
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The following are the recommendations for the sterilization of Synthes devices:
<table>
<tr><th>Cycle Type</th><th>Minimum Sterilization Exposure Time (minutes)</th><th>Minimum Sterilization Exposure Temperature</th><th>Minimum Dry Time*</th></tr>
<tr><td>Prevacuum</td><td>4</td><td>132°C (270°F)</td><td>20 minutes</td></tr>
</table>
*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, 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.

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, FDA-cleared sterilization barriers (e.g. wraps, pouches or containers) should be used by the end-user for packaging terminally sterilized devices.
Most devices are designed to be sterilized assembled unless:

Etched with "Disassemble for Sterilization";
The graphic case is not configured for the assembled device or
According to instructions in product specific information.

<u>Immediate-Use Steam Sterilization is only intended for individual instruments</u>.
Synthes does not support sterilizing loaded graphic cases or implants using this method. The following parameters are to be used when using Immediate-use steam sterilization:

Unwrapped instrument
4 (four) minute exposure
A minimum 3 (three) pulse fractionated prevacuum cycle
132 °C (270 °F)

Exceptions listed in the Cautions section of this document are not intended for Immediate-Use Steam Sterilization. Refer to the technique guide or other supplemental instruction to determine if device needs to be disassembled for sterilization. Immediate-Use Steam Sterilization should be performed in accordance with current AORN and AAMI recommendations.

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Storage	Sterilized products should be stored in a dry, clean environment, protected from direct sunlight, pests, and extremes of temperature and humidity.
Additional Information	• Cleaning Agent Information: Synthes used the following cleaning agents during validation of these reprocessing recommendations. These cleaning agents are not listed in preference to other available cleaning agents which may perform satisfactorily – neutral pH enzymatic detergents (e.g. Prolystica 2X Concentrate Enzymatic Cleaner, Enzol, Endozime and Neodisher Medizym) and neutral pH detergents (e.g. Prolystica 2X Neutral Detergent). • The cleaning and sterilization information is provided in accordance with ANSI/AAMI ST81, ISO 17664, AAMI TIR 12, ANSI/AAMI/ISO 17665-1, ANSI/AAMI ST79 and AAMI ST77. • The recommendations provided above have been validated by the medical device manufacturer as being capable of preparing a non-sterile Synthes medical device. 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. • All users should be qualified personnel with documented expertise, competency and training. Users should be trained on hospital policies and procedures along with current applicable guidelines and standards. • Users should don appropriate personal protective equipment (PPE) when processing devices in accordance with the Department of Environmental and Occupational Health and Safety's (OSHA) bloodborne pathogen guidelines.
Manufacturer Contact	For further information, contact DePuy Synthes Customer Service Department at 1.800.523.0322.

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