MANUAL AND MECHANICAL CLEANING

For Trauma Recon System (TRS)

Limited Warranty and Disclaimer: DePuy Synthes USA products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed.

WARNING: In the USA, this product has labeling limitations. See package insert for complete information.

CAUTION: USA Law restricts these devices to sale by or on the order of a physician.

To order in the US, call DePuy Synthes Power Tools Customer Service: (800) 327-6887.

Not all products are currently available in all markets. Some devices listed in this Cleaning Chart may not have been licensed in accordance with Canadian law and may not be for sale in Canada. Please contact your sales consultant for items approved for sale in Canada.
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Mechanical/Automated Cleaning Instruction with Pre-cleaning for Trauma Recon System (TRS)

This information is provided in accordance with ISO 17664: 2004 and ANSI/AMI ST81:2004.

Important:
- Manual pre-cleaning prior to mechanical/automated cleaning/disinfection is important to ensure cannulations and other difficult to access sites are clean.
- Alternative cleaning/disinfection procedures other than the procedure described below (including manual pre-cleaning) have not been validated by DePuy Synthes Power Tools.

1 Disassemble
Disassemble device if applicable, and remove the battery or power module from casing or handpiece.

Battery/power modules and charger may be wiped with a cloth. Do NOT disinfect, immerse, or sanitize battery/power modules.

Note: The screw coupling of the Sagittal Saw Attachment, Long, 05.001.224, and the TRS Recon Saw, 05.001.240, completely disassemble from saw for cleaning.

2 Return batteries to charger
Return batteries/power modules to charger after each use.

Important: Do not sterilize batteries or power modules! Batteries/power modules will no longer function.

3 Remove debris
Remove debris

Rinse device under running cold tap water for a minimum of two minutes. Use a sponge, soft lint-free cloth, and/or soft-bristled brush to assist in the removal of gross soil and debris. Clean all cannulations, handpieces, and attachments, with the Cleaning Brush (516.101).

Manipulate all moving parts such as the triggers, release sleeves for attachments, mode switch, etc. under running cold tap water to loosen and remove gross debris.

Note: Do not use pointed objects for cleaning.

4 Spray with solution
Spray and wipe device using a neutral pH enzymatic solution or foam spray for a minimum of two minutes. Follow the enzymatic detergent manufacturer’s instructions for use for correct temperature, water quality, and concentration/dilution.

5 Clean with detergent
Clean device manually under running warm water using a neutral pH enzymatic detergent for a minimum of five minutes. Manipulate all moving parts under running water. Use a soft-bristled brush and/or soft lint-free cloth to remove all visible soil and debris. Follow the enzymatic detergent manufacturer’s instructions for use for correct temperature, water quality and concentration/dilution.

Note: For Sagittal Saw Attachment, Long, 05.001.224, and the TRS Recon Saw, 05.001.240, process the Screw Coupling in an ultrasonic cleaner using a neutral pH enzymatic cleaner for a minimum of 15 minutes.

6 Rinse with tap water
Rinse device thoroughly using running cool to lukewarm tap water for a minimum of two minutes. A syringe, pipette, or water jet to flush lumens and channels. Actuate joints, handles, and other movable device features in order to rinse thoroughly under running water.

Vacuums: inspect device. Repeat Steps 3-6 until no visible soil remains.

Note: Manual pre-cleaning as described above must be followed by the mechanical/automated cleaning procedure.

7 Load washing machine basket
Place articles in the specially designed trays for machine washing supplied by DePuy Synthes Power Tools. Ensure that all cannulations (handpiece and attachments), if applicable, are positioned vertically, i.e., in an upright position as shown.

Note: Never immerse the handpiece, lid or attachments in an ultrasonic bath or any other liquid as this could decrease the service life of the system.

8 Automated cleaning cycle parameters

<table>
<thead>
<tr>
<th>Step</th>
<th>Minimum time (minutes)</th>
<th>Temperature/water</th>
<th>Type of detergent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rinse</td>
<td>2</td>
<td>Cold tap water</td>
<td>N/A</td>
</tr>
<tr>
<td>Pre-wash</td>
<td>1</td>
<td>Warm water (40°C)</td>
<td>Neutral pH enzymatic cleaner</td>
</tr>
<tr>
<td>Cleaning</td>
<td>2</td>
<td>Warm water (40°C)</td>
<td>Neutral pH enzymatic cleaner</td>
</tr>
<tr>
<td>Rinse</td>
<td>5</td>
<td>De-ionized (DI)</td>
<td>N/A</td>
</tr>
<tr>
<td>Thermal disinfection</td>
<td>5</td>
<td>Hot DI water (95°C)</td>
<td>N/A</td>
</tr>
<tr>
<td>Dry</td>
<td>40</td>
<td>95°C</td>
<td>N/A</td>
</tr>
</tbody>
</table>

9 Inspect devices
Remove all debris from washing basket. Inspect the cannulations, coupling sleeves, etc. for visible soil. If necessary, repeat the manual pre-cleaning/automated cleaning cycle. Please refer to DePuy Synthes Power Tools Battery Operated Equipment Lubrication Chart after cleaning and prior to sterilization.

Precaution: Mechanical cleaning/disinfection is an additional stress for power equipment, especially for seals and bearings. Therefore, systems must be properly lubricated and serviced regularly.
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