• Trays and cases with lids may be wrapped in standard medical grade, steam sterilization wrap using the AAMI double wrap method or equivalent.

• The total weight of a wrapped instrument tray or case should not exceed 11.4kg/25lbs. When placed in a sterilization container with gasketed lid the total sterilization package should not exceed 16kg/35lbs.

• Any device capable of disassembly must be disassembled prior to placement in the case.

• All devices must be arranged to ensure steam penetration to all instrument surfaces. Instruments should not be stacked or placed in close contact.

• The user must ensure that the instrument case is not tipped or the contents shifted once the devices are arranged in the case. Silicon mats may be used to keep devices in place.

• Only devices manufactured and/or distributed by Zimmer should be included in Zimmer instrument trays. Zimmer validated reprocessing instructions are not applicable to Zimmer trays that include devices that are not manufactured and/or distributed by Zimmer.

Sterilization

• Disinfection is only acceptable as a precursor to full sterilization for reusable surgical instruments. See Table 6 for recommended minimum sterilization parameters that have been validated by Zimmer to provide a 10^6 sterility assurance level (SAL).

• The hospital is responsible for in house procedures for the reassembly, inspection, and packaging of the instruments after they are thoroughly cleaned in a manner that will ensure steam sterilant penetration and adequate drying. Provisions for protection of any sharp or potentially dangerous areas of the instruments should also be recommended by the hospital.

• Moist heat/steam sterilization is the preferred and recommended method for Zimmer orthopaedic instrument sets.

• Sterilizer manufacturer recommendations should always be followed. When sterilizing multiple instrument sets in one sterilization cycle, ensure that the manufacturer’s maximum load is not exceeded. Instrument sets should be properly prepared and packaged in trays and/or cases that will allow steam to penetrate and make direct contact with all surfaces.

• Ethylene oxide or gas plasma sterilization methods should not be used unless package inserts for the applicable product specifically provide instructions for sterilization using these methods.

• Gravity displacement sterilization cycles are not recommended because cycle times are too long to be practical.

Storage

• Sterile, packaged instruments should be stored in a designated, limited access area that is well ventilated and provides protection from dust, moisture, insects, vermin, and temperature extremes.

Hospital Responsibilities for Zimmer Loaner Instruments

• Orthopaedic surgical instruments generally have a long service life; however, mishandling or inadequate protection can quickly diminish their life expectancy. Instruments which no longer perform properly because of long use, mishandling, or improper care should be returned to Zimmer to be discarded. Notify your Zimmer representative of any instrument problems.

• Loaner sets should undergo all steps of decontamination, cleaning, disinfection, inspection, and terminal sterilization before being returned to Zimmer. Documentation of decontamination should be provided with instruments being returned to Zimmer.

Customer Service Information

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This Zimmer reprocessing manual and the associated Quick Reference Guide can be found at www.zimmer.com under the “Medical Professional” heading.

Contact your Zimmer representative or visit us at www.zimmer.com

Instrument Care, Cleaning and Sterilization

In accordance with ISO 17666

Table 6. Recommended Steam Sterilization Parameters

<table>
<thead>
<tr>
<th>Cycle Type</th>
<th>Temperature</th>
<th>Exposure Time</th>
<th>Dry Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>UK Prevacuum</td>
<td>134°C 273°F</td>
<td>3 bar 28.5psi</td>
<td>3 minutes 30 minutes</td>
</tr>
<tr>
<td>Prevacuum</td>
<td>132°C 270°F</td>
<td>1.86bar 27psi</td>
<td>4 minutes 30 minutes</td>
</tr>
<tr>
<td>Prevacuum</td>
<td>134°C 273°F</td>
<td>3 bar 28.5psi</td>
<td>18 minutes 30 minutes</td>
</tr>
<tr>
<td>Prevacuum</td>
<td>132°C 270°F</td>
<td>1.86bar 27psi</td>
<td>8 minutes 30 minutes</td>
</tr>
</tbody>
</table>

Note: The Sterilizer Manufacturer’s instructions for operation and load configuration should be followed explicitly.

Important Notice

• The instructions provided in this Quick Reference Guide have been validated by Zimmer as being capable of preparing orthopaedic devices for use. It is the responsibility of the Hospital to ensure that reprocessing is performed using the appropriate equipment and materials, and that personnel in the reprocessing facility have been adequately trained in order to achieve the desired result. Equipment and processes should be validated and routinely monitored. Any deviation from the processes from these instructions should be properly evaluated for effectiveness to avoid potential adverse consequences.

Warnings & Precautions

• Universal Precautions should be observed by all hospital personnel that work with contaminated or potentially contaminated medical devices. Caution should be exercised when handling devices with sharp points or cutting edges.

• Personal Protective Equipment (PPE) should be worn when handling or working with contaminated or potentially contaminated materials, devices and equipment. PPE includes gowns, masks, eye protection, gloves, face shields, and shoe covers.

• Do not place heavy instruments on top of delicate devices.

• Metal brushes or scouring pads must not be used during manual cleaning procedures. These materials may damage the surface and finish of instruments. Soft-bristled, nylon brushes and pipe cleaners should be used.

• Do not allow contaminated devices to dry prior to reprocessing. All subsequent cleaning and sterilization steps are facilitated by not allowing blood, body fluid, bone and tissue debris, saline, or disinfectants to dry on used devices.

• Saline or cleaning/disinfection agents containing alcohol, mercury, active chlorine, chloride, bromine, bromide, iodine or isodide are corrosive and should not be used.

• Instruments must not be placed or soaked in Ringers Solution.

• Only fresh water may be used as a final rinse.

• Mineral oil or silicone lubricants should not be used because they: 1) coat microorganisms; 2) prevent direct contact of the surface with steam; and 3) may cause damage to the surface.

Limitations & Restrictions

• Automated cleaning using a washer/disinfector alone may not be effective for orthopaedic instruments. A thorough, manual or combination manual/automated cleaning process is recommended.

• Neutral pH enzymatic and cleaning agents are recommended and preferred for cleaning Zimmer reusable devices. Alkaline agents with pH 12 may be used to clean stainless steel and some polymer instruments in countries where required by law or local ordinance; or where pristine devices such as Transmissible Spongiform Encephalopathy (TSE) and Creutzfeldt-Jakob Disease (CJD) are a concern. It is critical that alkaline cleaning agents be completely and thoroughly neutralized and rinsed from devices.

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Note: Drill bits, reamers, rasps and other cutting devices should be carefully inspected after processing with alkaline detergents to ensure that cutting edges are fit for use.

• Instruments must be thoroughly processed according to these instructions prior to use.

Conclusions

• Additional information is available in Zimmer document 97-5000-170-00 R3 which should be used in conjunction with this Quick Reference Guide.

• This guide also includes procedures for sterilization of Zimmer reusable devices and should be studied carefully. This manual supersedes Zimmer and Centerpulse instrument manuals published prior to June 2006.

• This guide includes processing instructions for all Zimmer reusable devices including legacy Centerpulse instruments marked with processing category codes [a, b, c, d]. All Zimmer devices may be safely and efficiently reprocessed using the manual or combination manual/automated cleaning instructions outlined in this manual.

• The user/processor should comply with local laws and ordinances in countries where reprocessing requirements are more stringent than those detailed in this manual.

• New and used instruments must be thoroughly processed according to these instructions prior to use.
Completely submerge instruments in enzyme solution and allow to soak for 20 minutes. Scrub using a soft-bristled, nylon brush until all visible soil has been removed.

Place prepared cleaning agents in a sonication unit. Completely submerge device in cleaning solution and sonicate for 10 minutes at 45-50 kHz.

Rinse device in purified water for at least 3 minutes or until there is no sign of blood or soil on the device or in the rinse stream. Thoroughly and aggressively flush lumens, holes and other difficult to reach areas.

Rinse (X2); Hot Softened Tap Water; 15 seconds

Enzyme Soak; 1 minute

Pre Wash; Cold Softened Tap Water; 2 minutes

Enzymatic soak and scrub followed by sonication. Detergent Wash; Hot Softened Tap Water; (64-66°C/146-150°F); 2 minutes

Hot Air Dry; (116°C/240°F); 7 to 30 minutes

Thermal Rinse; Hot Softened Tap Water; (80-93°C/176-200°F); 2 minutes

Preparation Before Cleaning

• Symbols or specific instructions etched on instruments or instrument trays and cases should be strictly followed.
• Where applicable, multi-component instruments should be disassembled for appropriate cleaning. Disassembly, where necessary is general self-evident. Care should be exercised to avoid losing small screws and components.

Preparation Before Cleaning

• All cleaning agents should be prepared at the use-dilution and temperature recommended by the manufacturer. Softened tap water may be used to prepare cleaning agents. Use of recommended temperatures is important for optimal performance of cleaning agents.

Note: Fresh cleaning solutions should be prepared when existing solutions become contaminated (bloody and/or turbid).

Table 1. Cleaning/Disinfection Options

<table>
<thead>
<tr>
<th>Method</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manual (Table 2)</td>
<td>Enzymatic soak and scrub followed by sonication.</td>
</tr>
<tr>
<td>Combination Manual/Automated (Table 3)</td>
<td>Enzymatic soak and scrub followed by an automated washer/disinfector cycle.</td>
</tr>
<tr>
<td>Automated (washer/disinfector) (Table 4)</td>
<td>Automated cycle - Not recommended without manual pre-cleaning.</td>
</tr>
</tbody>
</table>

Manual Cleaning/Disinfection Procedure

Note: If stainless steel instruments are stained or corroded, an acidic, anti-corrosion agent in an ultrasonic cleaner may be sufficient to remove surface deposits. Care must be taken to thoroughly rinse acid from devices. Acidic, anti-corrosion agents should only be used on an as needed basis.

Table 2. Manual Cleaning Steps

Step 1: Completely submerge instruments in enzyme solution and allow to soak for 20 minutes. Scrub using a soft-bristled, nylon brush until all visible soil has been removed.

Step 2: Place prepared cleaning agents in a sonication unit. Completely submerge device in cleaning solution and sonicate for 10 minutes at 45-50 kHz.

Step 3: Rinse device in purified water for at least 3 minutes or until there is no sign of blood or soil on the device or in the rinse stream. Thoroughly and aggressively flush lumens, holes and other difficult to reach areas.

Step 4: Repeat the sonication and rinse steps above.

Step 5: Rinse instrument in purified water for at least 3 minutes or until there is no sign of blood or soil on the device or in the rinse stream. Thoroughly and aggressively flush lumens, holes and other difficult to reach areas.

Step 6: Hot Air Dry; (116°C/240°F); 7 to 30 minutes

Step 7: Thermal Rinse; Hot Softened Tap Water; (80-93°C/176-200°F); 2 minutes

Step 8: Rinse; Hot Softened Tap Water; (64-66°C/146-150°F); 15 seconds

Step 9: Enzymatic soak and scrub followed by sonication.

Step 10: Rinse (X2); Hot Softened Tap Water; 15 seconds

Step 11: Enzyme Soak; 1 minute

Step 12: Pre Wash; Cold Softened Tap Water; 2 minutes

Automatic Washer/Disinfector Cycle

Table 4. Automated Washer/Disinfector Cycle Steps

Step 1: Pre Wash; Cold Softened Tap Water; 2 minutes

Step 2: Enzyme Spray, Hot Softened Tap Water; 20 seconds

Step 3: Enzyme Soak; 1 minute

Step 4: Rinse (K2); Cold Softened Tap Water; 15 seconds

Step 5: Detergent Wash; Hot Softened Tap Water; (64-66°C/146-150°F); 2 minutes

Step 6: Rinse (K2); Hot Softened Tap Water; 15 seconds

Step 7: Thermal Rinse; Hot Softened Tap Water; (80-93°C/176-200°F); 2 minutes

Step 8: Purified Water Rinse; (64-66°C/146-150°F); 10 seconds

Step 9: Hot Air Dry; (116°C/240°F); 7 to 30 minutes

Cleaning/Disinfection Options

• Commercially available, medical grade steam sterilization pouches or wrap may be used to package individual instruments. The package should be prepared using the AAMI double wrap or equivalent method.

Sterile Packaging

• Instruments made of metal or metal instruments paired with polymer components. These devices are tolerant of alkaline cleaning agents when followed by acidic neutralization and thorough rinsing. These devices may be cleaned with rust-removal agents.

Inspection, Testing, Maintenance & Lubrication

• Carefully inspect each device to ensure that all visible contamination has been removed. If contamination is noted, repeat the cleaning/disinfection process.

• Check the action of moving parts (e.g. hinges, boas-locks, connectors, sliding parts, etc.) to ensure smooth operation throughout the intended range of motion.

• Check instruments with long slender features (particularly rotating instruments) for distortion.

• Where instruments form part of a larger assembly, check that devices assemble readily with mating components.

• Hinged, rotating, or articulating instruments should be lubricated with a water soluble product (e.g. Instrument Milk or equivalent lubricant) intended for surgical instruments that must be sterilized. Some water-based instrument lubricants contain bacteriostatic agents which are beneficial. Manufacturer's expiration dates should be adhered to for both stock and use-dilution concentrations.

Processing Category Codes

Processing codes listed in Table 5. are etched on some instruments and provide information useful in the selection of cleaning agents with appropriate pH. Zimmer recommends that all devices (regardless of etching) are processed in accordance with the manual or combination manual/automated cleaning instructions contained in this reprocessing guide.

Table 5. Processing Category Codes

| Steel/metal Instruments without cannulated bores/ lumens or non-metal/ polymer handles, or other components. These devices are tolerant of alkaline cleaning agents when followed by acidic neutralization and thorough rinsing. These devices may be cleaned with rust-removal agents. | Steel/metal Instruments with cannulated bores/lumens but without non-metal/polymer handles or other components. These devices are tolerant of alkaline cleaning agents when followed by acidic neutralization and thorough rinsing. These devices can be cleaned with rust-removal agents. Cannulations and hollow spaces must be cleaned manually. |
| Instruments made of polymers or metal instruments paired with polymer components. These devices are tolerant of alkaline cleaning agents when followed by acidic neutralization and thorough rinsing. | Instruments made of metal or metal instruments paired with polymer components. These devices are tolerant of alkaline cleaning agents when followed by acidic neutralization and thorough rinsing. Cannulations and hollow spaces must be cleaned manually. |
| Devices made of titanium or aluminum alloys and/or having assembly/ disassembly or other reprocessing aids. These devices should be cleaned using the manual or combination manual/automated cleaning procedures provided in this manual. These devices should not be exposed to alkaline cleaning agents. | Devices made of titanium or aluminum alloys and/or having assembly/ disassembly or other reprocessing aids. These devices should be cleaned using the manual or combination manual/automated cleaning procedures provided in this manual. These devices should not be exposed to alkaline cleaning agents. |

Safety Precaution: The total weight of a wrapped instrument tray or case should not exceed 11.4 kg/25 lbs. These devices should not be exposed to alkaline cleaning agents.