

Reprocessing Instructions for AcuDriver Reusable Surgical Instruments



Manufacturer: Exactech, Inc

Devices: These instructions apply to the reprocessing of the AcuDriver[®] pneumatic-powered handpiece and accessories.

Reprocessing for surgical instruments distributed by Exactech are not covered by these instructions and must be provided by the manufacturer.

Cleaning and sterilization equipment varies in performance characteristics and must be validated accordingly. The reprocessing facility is responsible for the routine validation and monitoring of all equipment, materials and personnel used in their facility to ensure the desired results are achieved. These instructions have been validated as being capable of preparing Exactech reusable surgical instruments for reuse. Any deviations from these procedures must be evaluated for efficacy by the reprocessing facility.

WARNINGS	<p>These instructions <u>have not</u> been proven effective for sterilizing instruments contaminated with unconventional transmissible agents (prions) such as the causative agents of Creutzfeldt-Jakob Disease (CJD) and Bovine Spongiform Encephalopathy (BSE). It <u>should not</u> be assumed that the methods described are effective against such agents.</p> <p>Cleaning is an essential pre-requisite to ensure effective sterilization. Lumens, blind holes, cavities, serrations and joints require particular attention during cleaning. Failure to completely remove organic debris and/or cleaning residues may lead to inadequate sterilization and result in an increased probability of infection.</p> <p>Failure to thoroughly remove cleaning agents may lead to sensitivity and/or allergic reactions.</p> <p>Wear appropriate protective equipment and follow local infection control policies while handling contaminated instruments. This includes but is not limited to waterproof clothing, robust gloves and eye protection. Avoid splashing and creation of aerosols. Handle sharp instruments with care to avoid injury.</p> <p>Caustic substances and those containing a chemical make-up of highly acidic or alkaline-based solutions may cause corrosion and shorten instrument life. Instruments with anodized coatings are particularly sensitive to highly alkaline (pH>9) solutions. Exposure to temperatures above 137 °C (279 °F) may accelerate instrument degradation. Water impurities, such as alkali metal, metal and chloride ions may discolor or corrode instruments.</p> <p>Use potable tap water for final rinsing. Saline may cause deterioration of instrument surfaces. Corrosion, rusting and pitting may occur when blood and debris are allowed to dry on surgical instruments.</p> <p>Only legally marketed medical equipment, solutions and accessories should be used for reprocessing surgical instruments. Do not use non-absorbent tray accessories as these may cause condensation to pool and extend drying times.</p> <p>All non-sterile instruments must be thoroughly cleaned and sterilized prior to use. Exactech products labeled for "single use only" must not be reprocessed. Always clean and sterilize surgical instruments before returning them to Exactech.</p> <p>Never re-use osteotomes. They are provided sterile and are designed to be single-use instruments only.</p> <p>Do not lubricate. The handpiece is pre-lubricated. Lubrication of the AcuDriver handpiece may result in damage to the internal parts.</p> <p>Never immerse the AcuDriver handpiece or accessories completely. Immersion into any solution</p>
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	<p>will permanently damage the instrument by allowing liquid to enter and may corrode metal and delicate moving parts and break down internal lubricants. Immersion damage will void any warranty.</p> <p>Never clean the AcuDriver handpiece or accessories with liquid or chemical disinfectants, synthetic detergents, or oil-based soaps. This may damage the instrument and accessories.</p> <p>Do not ultrasonic clean the AcuDriver handpiece or accessories.</p> <p>Do not sterilize by Ethylene Oxide gas.</p> <p>Never sterilize the nitrogen regulator or immerse it in any solution.</p>
LIMITATIONS ON REPROCESSING	<p>Repeated reprocessing according to these instructions has a minimal effect on Exactech surgical instruments. The useful life is normally determined by a visual and/or functional evaluation prior to use.</p> <p>Never re-use osteotomes. They are designed to be single-use instruments only.</p>
INSTRUCTIONS	
Point of Use	<ul style="list-style-type: none"> • Remove gross debris immediately after use. • Modular instruments that were assembled as part of the surgery should be disassembled for cleaning. It is recommended that the Surgical Air Hose remain attached to the handpiece during cleaning. This will prevent water from entering the air intake port of the AcuDriver handpiece. • Remove excess soil with surgical wipes/sponges moistened with sterile water. Do not immerse the AcuDriver handpiece or accessories. • In order to ensure effective cleaning, do not allow soil to dry on instruments. Clean instruments as soon as possible after use.
Preparation before Cleaning	No particular requirements.
Cleaning – General Instructions	<p>The following cleaning guidelines are intended to supplement those supplied by equipment and solution manufacturers and local policies.</p> <p>Operate equipment in accordance with the equipment manufacturer's instructions and in consideration of any limitations of use. This includes characteristics of certain types of instruments that require special handling or which may not be adequately cleaned by the equipment. Select, prepare and use cleaning solutions in accordance with the equipment manufacturer's instructions. Special attention should be paid to specifications for detergent concentration, water temperature, water quality and maintenance schedules.</p> <p>In order to prevent damage to instruments, use only mild detergents.</p> <p>Modular instruments that were assembled as part of the surgery should be disassembled for cleaning. It is recommended that the Surgical Air Hose remain attached to the handpiece during cleaning. This will prevent water from entering the air intake port of the AcuDriver handpiece.</p> <p>Instrument cases and trays must be inspected for soil and cleaned according to the cleaning instructions below, if needed.</p> <p>Do not immerse the AcuDriver Instruments.</p> <p>Do not lubricate the AcuDriver Instruments. The handpiece is pre-lubricated. Lubrication of the AcuDriver handpiece may result in damage to the internal parts.</p> <p>Never clean the AcuDriver handpiece or accessories with liquid or chemical disinfectants, synthetic detergents, or oil-based soaps.</p> <p>Do not ultrasonic clean the AcuDriver handpiece or accessories.</p>

Cleaning – Manual	<p>Instruments must be thoroughly cleaned. Thorough cleaning is an essential prerequisite for effective steam sterilization.</p> <p>Never sterilize the nitrogen regulator or immerse it in any solution.</p> <ul style="list-style-type: none"> • It is recommended that the Surgical Air Hose remain attached to the handpiece during cleaning. This will prevent water from entering the air intake port of the AcuDriver handpiece. • Thoroughly scrub the instrument and accessories with a soft bristled, non-metallic brush with a warm mild soap solution. Pay close attention to threads, crevices, seams, and any hard-to-reach areas. Actuate any moveable mechanisms, such as the trigger, to free trapped soil. All traces of blood and debris should be removed. • Rinse thoroughly under warm, running potable tap water for a minimum of two (2) minutes followed by rinsing under at least one (1) gallon of distilled water. When rinsing, pay particular attention to threads, crevices, seams, and any hard-to-reach areas. Actuate moveable parts such as the trigger while rinsing. Removal of cleaning residues is an essential prerequisite for effective steam sterilization. Keep the nose of the ACUDRIVER Handpiece and Osteotome Handle/Extractor pointed downward when rinsing. • Carefully dry using an absorbent, non-shedding cloth. • After cleaning, visually inspect all instruments to ensure the complete removal of soil from surfaces, lumens, and holes. No visible contamination should remain. Removal of all visible organic material and other residue is required prior to steam sterilization. • If contamination is still present, reclean the instrument. 									
Cleaning - Automated	<ul style="list-style-type: none"> • Automated cleaning is not recommended for the AcuDriver instrumentation. 									
Disinfection	<p>Instruments must be terminally sterilized prior to surgical use. See sterilization instructions.</p>									
Instrument Inspection	<ul style="list-style-type: none"> • Visually inspect for damage and wear, (e.g., corrosion, discoloration, nicks, damage to the connection). • If damage or wear is found, do not use the instrument and contact the Exactech sales representative or Exactech customer service for disposition. 									
Packaging	<ul style="list-style-type: none"> • Assemble components into their respective tray positions and place lid on tray. Proper positioning of items is essential for adequate steam penetration and aeration during processing. Steam must contact all instrument surfaces in order to ensure effective sterilization. • Do not crimp the Surgical Air Hose when closing the sterilization case lid. • Wrap entire tray in sterilization wrap material and apply label to indicate contents. Sterilization wraps must allow adequate steam penetration, aeration and protection against microbial penetration. Sterilization wraps should be approved for clinical use. In the United States only sterilization wraps cleared for marketing by the Food and Drug Administration (FDA) should be used. 									
Sterilization	<p>DO NOT STERILIZE BY ETHYLENE OXIDE GAS.</p> <p>Perform a pre-vacuum steam cycle using one of the following cycles:</p> <table border="1" data-bbox="358 1367 1094 1539"> <thead> <tr> <th>Temperature</th> <th>Minimum Exposure Time</th> <th>Drying Time</th> </tr> </thead> <tbody> <tr> <td>132°C (270°F)</td> <td>Four (4) minutes</td> <td>30 minutes</td> </tr> <tr> <td>134°C (273°F) *see below</td> <td>Three (3) minutes</td> <td>30 minutes</td> </tr> </tbody> </table> <p><i>*The 134°C / 3-minute sterilization cycle is not considered by the Food and Drug Administration to be a standard sterilization cycle. This cycle is not for use in the USA and this cycle is not to be used for the inactivation of prions. It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the Food and Drug Administration for the selected sterilization cycle specifications (time and temperature).</i></p> <ul style="list-style-type: none"> • Do not stack instrument cases in the autoclave. • Ensure autoclave equipment achieves and maintains the proper time, temperature, and 	Temperature	Minimum Exposure Time	Drying Time	132°C (270°F)	Four (4) minutes	30 minutes	134°C (273°F) *see below	Three (3) minutes	30 minutes
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	<p>pressure.</p> <ul style="list-style-type: none"> • Operate equipment in accordance with the equipment manufacturer's instructions. • When sterilizing multiple instrument sets in one autoclave cycle ensure the maximum load stated by the equipment manufacturer is not exceeded.
Storage	<ul style="list-style-type: none"> • Store and transport sterile instruments in such a way as to maintain sterility and functional integrity. • Store instrument in dry, clean, well-ventilated environments away from floors, ceilings and outside walls. • If sterilization is performed by an outside contract facility, protect the wrapped devices from contamination by additional covering. • Segregate sterile instruments from non-sterile items. Label sterile instruments to identify sterility status and ensure use in a first in, first out (FIFO) order. • Do not use instruments if the sterilization wrap is opened, damaged or wet.
Manufacturer Contact	<p>For additional product information, please contact customer service: Exactech Inc. 2320 NW 66th Court Gainesville, Florida 32653-1630 USA Phone: (352)-377-1140 (800)-392-2832 Fax: (352)-378-2617 www.exac.com</p>