

## Instrument Care, Cleaning and Sterilization Instruction

*In accordance with ISO 17664 – 2004*

<b>Manufacturer</b>	Ultradent Products Inc.
<b>Reusable Instrument Description</b>	Manual dental hand instruments.
<b>Scope</b>	These instructions are applicable to the processing of stainless steel dental hand instruments. They are applicable before first use and each reuse. Stainless steel dental hand instruments are supplied mechanically clean but are not sterile. They should therefore be sterilized before first use.
<b>Warnings</b>	<ol style="list-style-type: none"> <li>1. Used instruments should be considered as contaminated and appropriate handling precautions should be taken during reprocessing. Gloves, eye protection and a mask should be worn. Other measures may be required if there are specific infection or cross-contamination risks from the patient.</li> <li>2. Automated cleaning may not be effective. A thorough, manual cleaning process is Recommended.</li> <li>3. Where applicable, disassemble instruments prior to cleaning.</li> <li>4. Cleaning agents with chlorine or chloride as the active ingredient are corrosive to stainless steel and must not be used. Enzymatic and cleaning agents with neutral pH are recommended.</li> </ol>
<b>Reprocessing Limitations</b>	Repeated processing, according to the instructions below, has minimal effect on Ultradent reusable manual instruments. End of life is normally determined by wear and damaged due to use.

### INSTRUCTIONS

<b>Point of Use</b>	Remove excess body fluid and tissue with a disposable, non-shedding wipe and cover with a damp cloth. Body fluids and tissue should not be allowed to dry on instruments prior to cleaning.
<b>Containment/ Transportation</b>	<ol style="list-style-type: none"> <li>1. Universal precautions for handling contaminated/biohazardous materials should be observed.</li> <li>2. Instruments should be cleaned within 30 minutes of use to minimize the potential for drying prior to cleaning.</li> </ol>
<b>Manual Cleaning Procedure</b>	If hand cleaning is the only available option, the instruments should be cleaned in a sink reserved for the purpose. Rinse the instrument under running cold water and, keeping the instrument immersed, brush thoroughly away from the body using a cleaning or cleaning/disinfecting agent validated for use on dental instruments. Follow the agent manufacturers' instructions. Care should be taken to avoid spreading contaminants by spraying or splashing during the brushing process. Use wire brushes with caution as brass particles may result in galvanic corrosion and steel particles may cause discolouration of stainless steel. Particular attention is required when cleaning instruments with hinges, blind holes, lumens or long cannulae. The use of a water jet, appropriate brush or stilette may be required.
<b>Automated Cleaning Procedure</b>	<p>Auto cleaning is the only recommended method and should use only validated washer disinfectors and appropriate agents validated for use on dental instruments with the selected machine. Follow the washer disinfectant and the cleaning agent manufacturers' instructions. The minimum water temperature shall be 80°C.</p> <p>After cleaning inspect the instruments, with the aid of magnification if necessary, to ensure that all contamination has been removed. Repeat the cleaning process if necessary, cleaning by hand and re-inspecting before repeating the auto-cleaning phase.</p>

<b>Disinfection</b>	Disinfection is the only acceptable as an adjunct to full sterilization for reusable dental instruments. See sterilization section below.
<b>Packaging</b>	<ol style="list-style-type: none"> <li>1. If using a vacuum autoclave pack the instruments in dedicated instrument trays or pouches validated for sterilization. Hinged instruments should be packed in the open position.</li> <li>2. If using a non-vacuum autoclave the instruments must not be packed or wrapped but placed on open trays to obviate the need for unnecessary handling. Hinged instruments should be packed in the open position.</li> </ol> <p><i>Note: National legislation may require that instruments are wrapped in pouches for processing in either type of autoclave.</i></p>
<b>Sterilization</b>	Autoclave the instruments for a holding time not less than three minutes at a temperature of between 134 and 137°C. Other validated time/temperature regimes may be used. The holding time is the minimum time for which the minimum temperature is sustained.
<b>Storage</b>	The instruments should be stored in the sterilization container (instrument tray or pouch) until required. Containers or pouches must be dry before opening to avoid recontamination of the contents with water. Storage should be in dry, clean conditions and at ambient temperature.
<b>Validation</b>	<p>These processes have been validated as being capable of preparing stainless Steel dental hand instruments for reuse.</p> <p><b>Note: It remains the responsibility of the reprocessor to ensure that the reprocessing as actually performed using the equipment, materials and personnel in the reprocessing facility achieve the required results. This may require validation and monitoring of the process. Any deviation from these instructions should be properly evaluated for effectiveness and potential adverse results.</b></p>
<b>Customer Service Information</b>	<p>Ultradent Products Inc.  505 West 10200 South  South Jordan, UT 84095  U.S.A.</p> <p>Inside the U.S.A. dial (800) 552-5512  Outside the U.S.A. dial the local international access code followed by +1-801-572-4200</p>