1. If the Handpiece is received in a defective condition, do not use and notify Alcon immediately:

GENERAL CAUTION: U.S. Federal Law restricts this device to sale by or on the order of a physician.

CAUTION: Do not use the Handpiece if it is damaged, if its packaging has been tampered with, or if the instructional labels are missing or illegible. The Operator's Manual, which is provided with the console, includes in-depth material intended to familiarize the Operating Room Staff with the controls and functions of the console.

CAUTION: U.S. Federal Law restricts this device to sale by or on the order of a physician.

2. Each time the Handpiece is connected to the driving console, it performs a check cycle. If the Handpiece performs improperly and fails the check cycle, remove it from the driving console and return it to Alcon for evaluation.

3. Use care in handling the Handpiece, particularly when cleaning. Extra attention to protecting the nosecone area should be taken. Always clean the Handpiece over a surface cushioned with a pad or rubber mat.

4. This Handpiece is to be used only with approved ALCON® surgical systems. See the particular Operator's Manual of the surgical system for a list of appropriate Handpieces for that system.

5. In the event of any difference between this document and the driving console Operator's Manual, please use the information in this Directions-For-Use. If you have questions, please contact Alcon.

6. Be sure the handpiece connector is dry before connecting it to the console.

7. Do not ultrasonically clean the Handpiece. Ultrasonic cleaning of this handpiece will cause irreparable damage.

8. Never immerse the handpiece in liquid after autoclaving; allow it to air cool for at least 15 minutes.

**WARNINGS:**

1. This Handpiece is provided as a non-sterile unit and must be cleaned and sterilized prior to use.

2. Before each use, the Handpiece and power cord should be inspected for damages (e.g. nicks, crimps, dents, exposed wire). If the Handpiece is damaged, it should be immediately removed from service. Use of damaged Handpiece may result in serious permanent patient injury.

3. During any phacoemulsification procedure, metal particles may result from inadvertent touching of the phacoemulsification tip with a second instrument. Another potential source of metal particles resulting from any ultrasonic handpiece may be the result of ultrasonic energy causing micro abraisions of the ultrasonic tip.

4. If in the medical opinion of the physician a patient with a prion related disease undergoes a high risk procedure, the instrument should be destroyed or be processed according to local requirements.

**DESCRIPTION:** Each package contains one ultrasonic Handpiece.

**DIRECTION FOR USE:** The following cleaning and sterilization instructions provide a method for effectively cleaning and sterilizing the CENTURION® OZIL® Handpiece per EN ISO 17664. Due to the potential for Toxic Anterior Segment Syndrome (TASS), Alcon does not recommend the use of enzymatic cleaners, detergents, or disinfectant solutions. If however, local jurisdictions mandate their use relative to ophthalmic instruments, the materials of construction are compatible with both, up to a pH of 11.3, when the enzymatic chemicals, detergents, or disinfectant solutions are completely rinsed/neutralized immediately after cleaning/processing per your surgical facility's standard procedure.

1. Thoroughly clean the handpiece before initial use and IMMEDIATELY after each subsequent use. Do not store or allow the handpiece to dry after use until thoroughly cleaned.


   Perform the following steps to thoroughly clean the handpiece.

   **Step One:** Remove the irrigation and aspiration tubing from the handpiece.

   **Step Two:** Unplug the handpiece connector from the console and install the protective cap.

   **Step Three:** Remove the infusion sleeve and tip from the handpiece using a tip wrench and discard according to surgical facility guidelines.

   **Step Four:** Wipe any residue from the handpiece with a soft, clean, lint free non-abrasive cloth and rinse the handpiece with room temperature sterile, deionized water to remove any remaining debris. If necessary, wash the exterior of the handpiece using a soft bristled cleaning brush.

   **Step Five:** Using a syringe, push a minimum of 120cc of room temperature sterile, deionized water through both the irrigation and aspiration paths.

   **Step Six:** Using the same syringe, flush both ports with a minimum of 60cc of air.

   **Step Seven:** Dry the exterior surfaces of the handpiece and cable with a soft, clean, lint free non-abrasive cloth.

   **Step Eight:** Visually inspect to ensure the Handpiece is clean and dry. Repeat the process as needed.

   **Step Nine:** Place the cleaned handpiece and cable in the sterilization tray to prevent damage to connector and handpiece during storage and autoclaving, or wrap to prevent damage in preparation for autoclaving.

3. **Sterilization:** Sterilize the handpiece using a steam sterilization cycle. The sterilization instructions provided in Table 1 below have been validated by Alcon Laboratories, Inc. as being CAPABLE of sterilizing the CENTURION® OZIL® Handpiece for re-use. It remains the responsibility of the processor to ensure that the processing as actually performed using equipment, materials and personnel in the facility achieve the desired result. This requires verification and routine monitoring of the process. Likewise any deviation by the processor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences. Please refer to nationally recognized standards, or to your facility’s standard procedures.

**Note:** Due to the potential for the accumulation of particulate and bioburden residues in the sterilizer water reservoirs, it is the surgical facility’s responsibility to properly maintain the equipment and their associated filters to ensure the introduction of steam into the Handpiece is contaminant free at levels acceptable per the surgical facility’s requirements.

**Table 1 - STERILIZATION TEMPERATURE AND TIME SETTINGS**

<table>
<thead>
<tr>
<th>Sterilizer Type</th>
<th>Configuration</th>
<th>Minimum Temperature</th>
<th>Minimum Exposure Time (Minutes)</th>
<th>Minimum Drying Time (Minutes)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gravity Displacement</td>
<td>Wrapped</td>
<td>132°C (270°F)</td>
<td>15</td>
<td>15</td>
</tr>
<tr>
<td>Gravity Displacement</td>
<td>Unwrapped</td>
<td>132°C (270°F)</td>
<td>10</td>
<td>N/A</td>
</tr>
<tr>
<td>Pre-vacuum</td>
<td>Wrapped</td>
<td>130°C (275°F)</td>
<td>3</td>
<td>16</td>
</tr>
<tr>
<td>Pre-vacuum</td>
<td>Unwrapped</td>
<td>132°C (270°F)</td>
<td>4</td>
<td>N/A</td>
</tr>
</tbody>
</table>
4. After sterilization, allow the components to cool.
5. After transport to the driving console for the next use, refer to your driving console Operator’s Manual for proper surgical setup.
6. Refer to Alcon’s Pack/Tip directions for use for proper assembly of the tip to the Handpiece.
7. There are not specific limits for the time of conditions of storage.
8. Reference: "EN ISO 17664: Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices.

Definitions for symbols that may appear on product labels:

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>SEE DIRECTIONS FOR USE</td>
<td>MANUFACTURER</td>
</tr>
<tr>
<td>DOES NOT CONTAIN LATEX OR DRY NATURAL RUBBER</td>
<td>DATE OF MANUFACTURE</td>
</tr>
<tr>
<td>MAGNETIC RESONANCE ENVIRONMENT UNSAFE</td>
<td>AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY</td>
</tr>
</tbody>
</table>

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