

Cryo-Tip Probe - Care, Cleaning and Sterilization

(In accordance with ISO 17664)

Device(s):

All reusable Cryo-Tip Probes supplied by Keeler Ltd. as part of the Keeler Cryomatic ophthalmic cryosurgery system.

Warnings and Precautions

General	<p>Cryo-Tip probes are precision instruments and should be handled with care at all times. It is important that the flexible hose does not become kinked during normal use, storage, transportation or reprocessing. If this does occur the probe must be returned to the manufacturer for repair.</p> <p>Do not obstruct the vent holes on the disposable probe (located on the tube) and the reusable probe.</p>
Limitations On Reprocessing	<p>Repeated processing has minimal effect on these instruments. End of life is normally determined by wear and damage due to use rather than reprocessing.</p> <p>Cryo-Tip Probes are tolerant of alkaline cleaning agents when followed by acidic neutralization and/or thorough rinsing.</p> <p>Gamma irradiation or dry air sterilization methods involving temperatures in excess of 139°C should not be used since they may damage the Cryo-Tip probe.</p>

Instructions

	<p>Before use, the complete Cryo-Tip Probe must be sterilized. Sterilization by steam autoclave has been validated.</p>
Point Of Use	<p>No particular requirements although excess soiling can be removed with disposable cloth/paper wipe.</p>
Containment and Transportation	<p>Care should be taken to ensure that the flexible hose of the Cryo-Tip probe is not coiled too tightly or kinked during reprocessing.</p> <p>Used instruments must be transported to the central supply in closed or covered containers to prevent unnecessary contamination risk.</p> <p>It is recommended that instruments are reprocessed as soon as is reasonably practical following use.</p>
Preparation For Cleaning	<p>No particular requirements. Disassembly not required.</p>
Cleaning and Disinfection: Automated	<p>Use equipment meeting relevant standards¹ and which uses the following typical automated sequence:</p> <ul style="list-style-type: none">• Pre-Rinse/Wash• Detergent wash; hot water using (detergent specified by the washer/disinfectant manufacturer)• Thermal rinse; hot purified water (80-93°C/176-200°F); 1 minute• Hot Air Dry <p>¹ <i>HTM2030 and BS EN ISO 15883 or equivalent</i></p>

Instructions Contd.

<p>Cleaning: Manual</p>	<p>Not recommended – use an automated system if possible. If manual cleaning is carried out care should be taken not to use abrasive materials on the Cryo-Tip probe stem.</p>																			
<p>Drying</p>	<p>Hot Air Dry</p>																			
<p>Maintenance</p>	<p>Check for obvious signs of damage – return for manufacturer if any damage is noted.</p>																			
<p>Inspection and Function Testing</p>	<p>Visually inspect for damage and wear. Check probe tips for signs of bending, distortion or other damage. Connect Cryo-Tip Probe to ‘Cryomatic’ console to check correct and smooth function of probe quick release coupling.</p>																			
<p>Packaging</p>	<p>Pouch or Tray - Refer to the product-specific instruction manual for compatibility with steam sterilization.</p>																			
<p>Cleaning and Disinfection: Automated</p>	<p>Cryo-Tip Probe must be cleaned prior to sterilization. Thorough cleaning removes both micro-organisms and organic material. Failure to remove organic material decreases effectiveness of the sterilization procedure. After cleaning, make sure that the instrument is carefully dried.</p> <p>Place the instruments in appropriate instrument trays or pouches. Wrap or seal them adequately. Do not seal the instruments in close contact with each other as this might impair the sterilization effect.</p> <p>Never rinse the instruments with cold water for cooling. Be careful when unloading the autoclave, the contents may be hot.</p> <p>Make sure that the sterile package of the instruments is not damaged. If the package has been perforated, if the sealing has been opened, if the packaging is wet or if the packaging is damaged in any other way, repackage and then re-sterilize the instruments.</p> <p>Disinfection is only acceptable as a precursor to full sterilization for reusable surgical instruments. See Table 1 for recommended sterilization parameters using equipment meeting relevant standards.</p> <p>Sterilizer manufacturer recommendations should always be followed. When sterilizing multiple probes in one sterilization cycle, ensure that the manufacturer’s maximum load is not exceeded.</p> <table border="1" data-bbox="454 1630 1412 1848"> <thead> <tr> <th colspan="5">Table 1</th> </tr> <tr> <th>Sterilizer type</th> <th>Temperature</th> <th>Pressure</th> <th>Exposure time</th> <th>Drying time</th> </tr> </thead> <tbody> <tr> <td>Pre-vacuum (porous load)</td> <td>134 – 137 °C (273-279 °F)</td> <td>-</td> <td>3 minutes</td> <td rowspan="2">20 minutes</td> </tr> <tr> <td>Gravity</td> <td>121-124°C (250-255°F)</td> <td>-</td> <td>30 minutes</td> </tr> </tbody> </table> <p>It is the responsibility of the user to validate any sterilisation process that deviates from these recommendations.</p>	Table 1					Sterilizer type	Temperature	Pressure	Exposure time	Drying time	Pre-vacuum (porous load)	134 – 137 °C (273-279 °F)	-	3 minutes	20 minutes	Gravity	121-124°C (250-255°F)	-	30 minutes
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Instructions Contd.

Storage

As the product's transport packaging is not designed for storage, do not store the product in the transport packaging. Use instrument tray systems for storage. Cryo-Tip probes should be coiled loosely during storage.

Store the sterile, Cryo-Tip probes in a clean and dry condition at room temperature.

- Do not expose the equipment to direct sun light.
- Do not expose the equipment to sources of X-ray radiation.
- Do not store the equipment in a location where liquids may splash.
- Do not store the equipment under environmental conditions such as:
 - high atmospheric pressure
 - high or low temperatures
 - high or low humidity
 - direct ventilation
 - direct sunlight
 - dust
 - salty or sulfurous air
- Do not store the equipment where there is a risk of flammable gases.

The storage life of sterilized instruments depends on the type of packaging and the storage conditions. Refer to national and local laws and guidelines.

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