



VISTA APEX

# Stropko™ Irrigator

REF 315260, 315265

**This instrument can be used with most air / water syringes using the 3-way dental syringe tip.**

## Instructions for Use:

- The air pressure to the syringe must be regulated down to between 4-7 psi (normal is 30-50 psi).
- When using for air-drying endodontic canals, reduce the air pressure to 1-3 psi and use only notched or side-vent needles.
- If the syringe has a “Quick Connector” remove the standard tip and replace it with the Stropko™ Irrigator. Insert Stropko™ Irrigator snugly into the air/water syringe (If using press ring style air/water handpiece, ensure that Stropko™ Irrigator is locked in).
- Use any luer-lock needle or tip. The desired tip must be completely screwed into the luer-lock hub on the Stropko™ Irrigator to prevent dislodgement during use.
- The luer tips used cannot have any extensions back into the instrument beyond the hub. Do NOT use sharp pointed injection-type needles or needle tips that are smaller than 27ga.
- Follow detailed reprocessing instructions contained within this IFU for cleaning and sterilizing the device between patients. Note - Reprocess the Stropko Irrigator separately from any used tips. Tips are typically “single use only” unless otherwise communicated by the tip manufacturer.

**Note:** According to the EU Medical Devices Regulation, users / patients are obliged to report serious events with a medical device to the manufacturer and to the competent authority of the country in which they occurred.

**Note:** Older 3-way syringes must have a small pin inserted below and passing behind the air and water buttons to prevent them from “popping out”. If the pin is not present, a newer version of the 3-way syringe must be acquired.

### Autoclave Parameters:

Do not exceed  
275°F or 135°C.

**Made in China**  
315260-I-V-ENG (7)

**Rx ONLY**



**MD**



**Emergo Europe**  
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# REPROCESSING INSTRUCTIONS

<b>Manufacturer:</b>	<b>Inter-Med, Inc.</b>
<b>Device:</b>	<b>Stropko™ Irrigator</b>
<b>WARNINGS</b>	<ul style="list-style-type: none"><li>• Appropriate PPE (gloves, safety glasses, scrubs or lab coat) should be worn when reprocessing medical devices.</li><li>• Do not disassemble devices.</li><li>• Do not use abrasive cleaners.</li><li>• Use neutral pH detergents during cleaning.</li><li>• Do not use with commercial sterilization wraps or pouches with sterilization indicators that leave a stain.</li><li>• For autoclavable products, do not sterilize with other products. Do not allow products to touch one another during autoclaving.</li><li>• Reprocess products as soon as possible after use.</li><li>• It is the user's responsibility to ensure that all reprocessing equipment used is properly validated, maintained, and calibrated in accordance with equipment specification and requirements.</li><li>• Reference should be made to the device's instructions for use / user manual for additional information which may be applicable to reprocessing.</li></ul>
<b>Limitations on process:</b>	<ul style="list-style-type: none"><li>• The products should be thoroughly inspected and tested for functionality after each reprocessing cycle. Devices should be replaced if any visible wear is seen, or if any noticeable decrease in product functionality is observed. Operator use and care will impact how long product will last. Contact Vista Apex with any questions.</li><li>• Vista Apex has validated the following number of reprocessing cycles for the products:<ul style="list-style-type: none"><li>- Stropko™ Irrigator: 80 cycles</li></ul></li></ul>

## REPROCESSING INSTRUCTIONS *(continued)*

<b>INSTRUCTIONS</b> <b>Initial treatment at the point of use:</b>	<ul style="list-style-type: none"><li>• Following clinical use, the product should be immediately rinsed with water and any channels should be flushed. Remove any visible debris or contamination using a lint free cloth.</li><li>• If reprocessing cannot be performed immediately, soak product in a mild, pH-neutral detergent until cleaning can be performed and maintain separation of soiled product from non-contaminated devices to avoid cross-contamination.</li></ul>
<b>Preparation before cleaning:</b>	<ul style="list-style-type: none"><li>• No disassembly is required for reprocessing. Do not attempt to disassemble product.</li><li>• Remove any visible gross debris and wipe using a lint free cloth. For non-electronic devices, water may also be used.</li></ul>
<b>Cleaning &amp; Disinfection:</b> <b>Automated</b>	<ul style="list-style-type: none"><li>• It is recommended to use a washer-disinfector meeting the requirements of ISO 15883. Products should be positioned such that they do not make physical contact with other parts in the washer-disinfector. Use a neutral-pH based cleaning agent. There are no known constraints on pressures and temperatures.</li></ul>
<b>Cleaning &amp; Disinfection:</b> <b>Manual</b>	<ul style="list-style-type: none"><li>• If cleaning and disinfecting the device manually, thoroughly wipe device using a single-use cloth dampened with a pH-neutral, aldehyde and alkylamine-free, alcohol-based, bactericidal, virucidal, fungicidal disinfectant solution (e.g. Alpet D2 Disinfectant or equivalent) following the manufacturer's instructions for use. Wipe device on all surfaces. Redampen cloth as needed.</li><li>• After 1-3 minutes of contact time, remove the disinfectant solution residue with a damp cloth. Use deionized water to dampen cloth. <b>NOTE:</b> Any lumens, grooves, or fluid paths should be cleaned in an equivalent manner using an appropriately sized non-abrasive cleaning brush following the same steps above.</li></ul>

## REPROCESSING INSTRUCTIONS *(continued)*

<b>Drying:</b>	<ul style="list-style-type: none"><li>• Dry with gauze or lint-free cloth. Air dry until liquid is no longer present (approximately 30 minutes).</li></ul>
<b>Maintenance, inspection and testing:</b>	<ul style="list-style-type: none"><li>• Thoroughly inspect and test the product for functionality after each reprocessing cycle. Confirm product is free of debris and not damaged. Devices should be replaced if any visible wear is seen, or if any noticeable decrease in product functionality is observed.</li></ul>
<b>Packaging:</b>	<ul style="list-style-type: none"><li>• No special packaging is required for sterilization.</li></ul>
<b>Sterilization:</b>	<ul style="list-style-type: none"><li>• Moist heat sterilize in accordance with ISO 17665-1 at 132°C or 134°C, 0.22mPa for at least 3 minutes (20 minute dry time).</li></ul>
<b>Storage:</b>	Store in a clean and dry location. Maintain separation of soiled from non-contaminated devices to avoid cross contamination.
<b>Additional information:</b>	No additional information needed for reprocessing.
<b>Manufacturer contact:</b>	<b>Inter-Med, Inc.</b> 2200 South Street Racine, WI 53404 USA +1-262-636-9755 info@vista-dental.com