



# Purevac<sup>®</sup> HVE System

## HVE Mirror Tips and Hose Adapter Starter Kit

Directions for Use

Please read carefully and completely before operating unit.



## TABLE OF CONTENTS

Overview	3
Intended Use	3
Contraindications	3
Warnings	3-4
Precautions	4
Adverse Reactions	4
Device Description	5
Unpacking the System	5
Preparation for Use	6-8
Infection Control Procedures	9-12
Specifications	13
Disposal of Unit	13

## OVERVIEW

The Dentsply Sirona HVE Mirror Tip and Hose Adapter Starter Kit offers a new and unique dental solution for high volume evacuation (HVE). The kit includes three (3) HVE Mirror Tips with an ergonomic unibody design and built-in mirror that allows for evacuation, illumination, retraction, and visualization with one hand. The HVE Hose Adapter allows the HVE Mirror Tip to be used in the most effective and comfortable manner, with a lightweight, flexible, and durable hose that provides greatly improved ergonomic support. The HVE Hose Adapter connects directly to a standard 11 mm HVE valve and also includes a 360° swivel connection for the HVE Mirror Tip and a holster to secure the system when not in use.

## INTENDED USE

The Dentsply Sirona HVE Mirror Tip and Hose Adapter Starter Kit is intended to provide oral high volume evacuation, visualization, illumination, and retraction during dental procedures. The device is intended to be used by trained dental professionals only.

## CONTRAINDICATIONS

There are no known contraindications.

## WARNINGS

- Only use compatible HVE tips with the Dentsply Sirona HVE Hose Adapter.
- Sterilizing the HVE Hose Adapter will cause component damage. Disinfect the HVE Hose Adapter using only the tested and approved disinfectants listed in the Infection Control Procedures Section.
- The HVE Mirror Tips must be steam sterilized before first use and between patients to prevent patient cross-contamination. See Infection Control Procedures Section.
- The HVE Mirror Tip is designed to last up to 100 reprocessing cycles and the HVE Hose Adapter is designed to last up to 2,500 reprocessing cycles. Use of the device beyond its useful life may cause damage to equipment and increases risk of patient cross-contamination.

- It is the responsibility of the Healthcare Professional to determine the appropriate uses of this product and to understand:
  - the health of each patient
  - the dental procedures being undertaken
  - applicable industry and governmental agency recommendations for infection control in dental healthcare settings
  - requirements and regulations for safe practice of dentistry
  - these Directions for Use in their entirety
- Inspect the device before each use for worn, loose, or damaged parts. Do not attempt to use the device unless the HVE Mirror Tip is properly installed. A loose HVE Mirror Tip could separate from the HVE Hose Adapter or HVE valve. Reinstall the HVE Mirror Tip or replace any damaged parts as necessary.
- Never install the HVE Hose Adapter or HVE Mirror Tip while the HVE system is operating.
- Dispose of the HVE Mirror Tip and HVE Hose Adapter according to CDC Guidelines for Infectious Waste and Federal, State, and Local regulations.

#### PRECAUTIONS

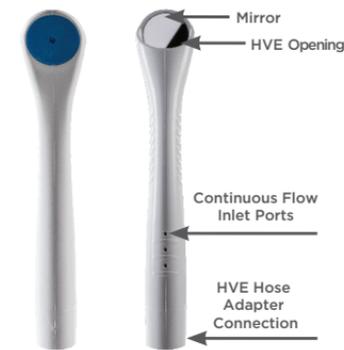
- Before using this product, carefully read and follow all instructions and save them for future reference. Observe all precautions and warnings.
- The HVE Hose Adapter can only be used with compatible HVE tips (15 mm) and was designed for the HVE Mirror Tip.
- The HVE Mirror Tip can only be used with compatible HVE valves (11 mm) and the HVE Hose Adapter.
- As with all dental procedures, use universal precautions (i.e., wear face mask, eyewear, face shield, gloves, protective gown, etc.).
- Oil and/or dirt may damage the HVE Hose Adapter's 360° swivel functionality.
- Take precaution during use with other dental instruments to avoid damage to the mirror and plastic.

#### ADVERSE REACTIONS

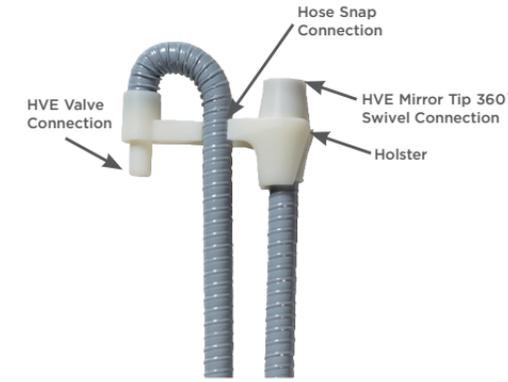
There are no known adverse reactions.

#### DEVICE DESCRIPTION

##### HVE Mirror Tip



##### HVE Hose Adapter



#### UNPACKING THE SYSTEM

As you unpack your Dentsply Sirona HVE Mirror Tip and HVE Hose Adapter Starter Kit, verify that the following components are included:

(1) HVE Hose Adapter, (3) HVE Mirror Tips, (1) Directions for Use

\*Before patient use, HVE Mirror Tips must be cleaned and sterilized. Go to “Infection Control Procedures” for reprocessing instructions.

## PREPARATION FOR USE

Method	Figure
Remove the HVE Hose Adapter (Figure 1) and three pack of HVE Mirror Tips from packaging.	 Figure 1
Locate the existing HVE valve (Figure 2) on your dental chair.	 Figure 2

## Method

Take the HVE Hose Adapter and position for insertion into the HVE valve (Figure 3).

Fully and securely insert the HVE Hose Adapter into the HVE valve (Figure 4).

Ensure the HVE Hose Adapter sits securely in the existing HVE valve (Figure 5).

## Figure



Figure 3



Figure 4



Figure 5

Method	Figure
<p>Take one HVE Mirror Tip (Figure 6) and insert directly into the HVE Hose Adapter (Figure 7).</p> <p>Ensure the HVE Mirror Tip is secure in the HVE Hose Adapter.</p> <p><b>*Before patient use, HVE Mirror Tips must be cleaned and sterilized. Go to “Infection Control Procedures” for reprocessing instructions.</b></p>	 <p>Figure 6</p> <p>Figure 7</p>
<p>Ensure the operatory suction system is on. Refer to the manufacturer's instructions for use.</p> <p>On the chair's HVE valve, switch the lever from off to on.</p> <p>Once on, suction should be flowing through the HVE Mirror Tip and ready for use.</p>	

## INFECTION CONTROL PROCEDURES

INSTRUCTIONS FOR REPROCESSING THE HVE MIRROR TIP		
Reprocessing Step	Method	Warning
<b>Point of Use</b>	<ul style="list-style-type: none"> <li>Turn suction off by switching the lever from on to off on existing HVE valve.</li> <li>Remove the HVE Mirror Tip from the HVE Hose Adapter.</li> <li>It is recommended that instruments are reprocessed as soon as is reasonably practical following use.</li> </ul>	<ul style="list-style-type: none"> <li>Do not attempt to remove the HVE Mirror Tip from the HVE Hose Adapter while the HVE system is operating.</li> </ul>
<b>Cleaning</b>	<ul style="list-style-type: none"> <li>Remove gross soil by rinsing under water of at least drinking quality.</li> <li>Prepare enzymatic instrument cleaning solution per the manufacturer's recommendation in a soaking container or ultrasonic bath.</li> <li>Place the HVE Mirror Tip in the solution for the time specified by the solution manufacturer for cleaning.</li> <li>Rinse the HVE Mirror Tip under running water of at least drinking quality for a minimum of 30 seconds to remove detergent residue.</li> <li>Allow the HVE Mirror Tip to dry.</li> <li>Visually inspect the HVE Mirror Tip for visible soil. If visible soil is present, repeat the cleaning procedure.</li> </ul>	<ul style="list-style-type: none"> <li>Do not use hard wire brushes to clean the HVE Mirror Tip as scratching can occur.</li> </ul> <p><b>Dentsply Sirona recommends the use of Resurge® Instrument Cleaning Solution.</b></p>

### INSTRUCTIONS FOR REPROCESSING THE HVE MIRROR TIP

Reprocessing Step	Method	Warning
<b>Sterilization</b>	<ul style="list-style-type: none"> <li>Place each HVE Mirror Tip in a separate steam-sterilization pouch.</li> <li>Place bagged HVE Mirror Tip into a steam sterilizer, per the sterilizer manufacturer's instructions.</li> <li>The following minimum sterilization cycles may be used:                             <ul style="list-style-type: none"> <li>Gravity steam sterilization – full cycle: 135 °C for 10 minutes.</li> <li>Pre-vacuum steam sterilization – full cycle: 121 °C for 15 minutes.</li> <li>Pre-vacuum steam sterilization – full cycle: 135 °C for 3 minutes.</li> <li>Steam flush/pressure pulse sterilization (e.g. STATIM) – full cycle: 134 °C for 3.5 minutes.</li> </ul> </li> <li>Alternate method: place non-bagged instruments into the steam sterilizer and run at the above listed cycles.</li> </ul>	<p><b>Before patient use, HVE Mirror Tips must be cleaned and sterilized.</b></p> <p><b>Dentsply Sirona recommends the use of Assure Plus® Self-Sealing Sterilization Pouches.</b></p> <p><b>Note: Instruments sterilized non-bagged should be used immediately.</b></p>

### INSTRUCTIONS FOR REPROCESSING THE HVE HOSE ADAPTER

Reprocessing Step	Method	Warning
<b>Point of Use</b>	<ul style="list-style-type: none"> <li>Turn suction off by switching the lever from on to off on existing HVE valve.</li> <li>Remove the HVE Mirror Tip from the HVE Hose Adapter.</li> </ul>	<ul style="list-style-type: none"> <li>Do not attempt to remove the HVE Mirror Tip from the HVE Hose Adapter while the HVE system is operating.</li> </ul>
<b>Cleaning &amp; Disinfection: Manual</b>	<ul style="list-style-type: none"> <li>To remove visible soil, thoroughly wipe the entire outer surface of the HVE Hose Adapter, including the entire length of the hose and the holster, with a new, single-use wipe in combination with an alcohol-based, tuberculocidal, cleaning and disinfecting solution. Use additional wipes as needed to ensure all visible soil is removed.</li> <li>Pay special attention to all seams and crevices while wiping.</li> <li>If soil is observed in the seam area of the HVE Hose Adapter, disassemble the unit by unscrewing the top plastic component (Figure 8), carefully removing the metal ring (Figure 9) and wiping the components separately (Figures 10 and 11). Once visually clean, place the metal ring back into the top plastic component and screw the plastic pieces back together.</li> </ul> <div style="display: flex; justify-content: space-around; margin-top: 10px;">     </div>	<ul style="list-style-type: none"> <li>Use only a disinfecting solution which is approved for its efficacy, EPA registered (and/or Health Canada approved), and use in accordance with the DFU of the disinfecting solution manufacturer.</li> </ul> <p><b>Dentsply Sirona recommends the use of VoloWipes® Disinfecting/Deodorizing/Cleaning Wipes.</b></p>

Figure 8

Figure 9

Figure 10

Figure 11

### INSTRUCTIONS FOR REPROCESSING THE HVE HOSE ADAPTER

Reprocessing Step	Method	Warning
<b>Cleaning &amp; Disinfection: Manual (continued)</b>	<ul style="list-style-type: none"> <li>To disinfect the device, use additional wipes as needed to ensure the entire outer surface, including seams and crevices, remain visibly wet for the contact time recommended by the solution manufacturer.</li> <li>Allow the device to air dry.</li> </ul>	<p><b>*VoloWipes® Disinfecting Wipes have a two minute contact time.</b></p>
<b>Cleaning: Internal</b>	<ul style="list-style-type: none"> <li>At the end of each day, clean the inside of the HVE Hose Adapter with evacuation cleaner following the manufacturer's directions for use.</li> </ul>	<ul style="list-style-type: none"> <li>The HVE Hose Adapter must be cleaned with evacuation cleaner at the end of each day to maintain its optimal function.</li> </ul> <p><b>Dentsply Sirona recommends the use of Purevac® SC Evacuation Cleaner.</b></p>

### SPECIFICATIONS

<b>Weight</b>	HVE Mirror Tip: 15.5 g or 0.55 oz. HVE Hose Adapter: < 109.7 g or < 3.87 oz.
<b>Dimensions</b>	HVE Hose Adapter Length: 1.524 m or 60 in. HVE Hose Adapter Swivel Connection I.D.: 15.875 mm or 0.625 in. HVE Hose Adapter Valve Connection O.D.: 11.252 mm or 0.443 in. HVE Mirror Tip Length: 128.53 mm or 5.06 in. HVE Mirror Tip Valve Connection O.D.: 15.215 mm or 0.599 in. HVE Mirror Tip Mirror Diameter: 17.85 mm or 0.703 in. HVE Mirror Tip Bore Opening Area: 90.406 mm <sup>2</sup> or 0.140 in <sup>2</sup>
<b>Operating Environment</b>	Ambient Temperature: -35 °C to 70 °C or -31 °F to 158 °F Relative Humidity Range: 10% to 95% non-condensing Atmospheric Pressure: 50 kPa to 106 kPa or 0.49 atm to 1.05 atm
<b>Transport and Storage Conditions</b>	Ambient Temperature: 10 °C to 40 °C or 50 °F to 104 °F Relative Humidity Range: 30% to 75% non-condensing Atmospheric Pressure: 70 kPa to 106 kPa or 0.69 atm to 1.05 atm

### DISPOSAL OF UNIT

Dispose of the system components in accordance with federal, state, and local laws.

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See webpage for  
instructions for use

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