integrated Control Head, suction tube, and twist-lock tail connection. The Control Head includes two Vacuum Levers to adjust suction in the upper and lower areas of the Mouthpiece, buttons to control the LED light source (on/off, white and amber color output) and its three levels of brightness, plus an integrated handle. The suction tube delivers both power and vacuum from the tail connection and the Power Vacuum Base (PVB) to the Control Head. See below for cleaning and disinfection instructions.

Power Vacuum Base

The Power Vacuum Base connects to the vacuum canister, which allows for suction control to the Isolite 3 device, an accessory device description

The Isolite 3 system is intended to be used with the unit’s built-in Isolite 3 Mouthpiece. The Mouthpiece is available in a wide range of sizes for effective isolation. Each Isolite 3 system is comprised of three main components: (1) Control Head Hose, (2) Vacuum Light Pipe, and (3) Power Vacuum Base.

Control Head Hose

The Control Head Hose (CHH) consists of an integrated Control Head, suction tube, and twist-lock tail connection. The Control Head includes two Vacuum Levers to adjust suction in the upper and lower areas of the Mouthpiece, buttons to control the LED light source (on/off, white and amber color output) and its three levels of brightness, plus an integrated handle. The suction tube delivers both power and vacuum from the tail connection and the Power Vacuum Base (PVB) to the Control Head. See below for cleaning and disinfection instructions.

Vacuum Light Pipe

The Mouthpiece attaches onto the Vacuum Light Pipe. The Vacuum Light Pipe provides dual channel suction and delivers the white and amber light into the Zyris Mouthpiece. See below for cleaning and sterilization instructions.

Power Supplies

The Power Vacuum Base provides electrical power to the Control Head Hose via the Power Vacuum Base. Optional power supplies included with the system can be connected to a standard 120v wall plug or integrated into a dental chair’s 24VAC power source.

ACCESSORIES

Cleaning Tip

The cleaning tip attaches to the control head and allows for connection to either a chairside integrated suction line cleaning system or a portable cleaning canister.

Control Head Hose O-Ring Maintenance Kit

The Control Head Hose O-Ring Maintenance Kit includes o-rings for the left and right levers, a tail connection, and Dow 111 silicone grease.

Power Vacuum Base O-Ring Maintenance Kit

The Power Vacuum Base O-Ring Maintenance Kit includes o-rings for the valve dial and accessory connectors, a valve dial seal, and Dow 111 silicone grease.

Double End Tube Brush

This two-in-one cleaning brush has bristles made of sturdy nylon fiber and a flexible handle.
plastic stem, which allows for the removal of biomatter and other debris from the suction channels.

Dow 111 Lubricant, Squeeze Tube
Sold Separately

For the o-rings to operate at peak efficiency, regularly lubricate them with Dow 111 Lubricant. This heavy-consistency dimethyl silicone compound resists a variety of organic and inorganic chemicals.

Barrier Sleeves
AIL0203 (non-sterile)
Sold Separately

Non-sterile Control Head Barrier Sleeves are available for additional protection from cross-contamination. Use of Barrier Sleeves does not eliminate the need to follow disinfecting and sterilization recommendations for the Control Head Hose and Vacuum Light Pipe.

Mouthpiece
CILXX0X (non-sterile)
Sold Separately

The non-sterile Mouthpiece is single-use only and available in various sizes. The Mouthpiece is constructed of a soft, flexible polymer for patient comfort while protecting the airway and soft tissue. The Mouthpiece is free of BPA, phthalates and does not contain natural rubber latex. For more information on sizes, go to zyris.com.

INTENDED USE

Isolite 3 is an illuminated dental isolation system for clinical use by dental professionals. The system was designed with the patient and clinician in mind. The Mouthpiece offers a soft, flexible bite block for patient comfort while providing intra-oral illumination, continuous suction, retraction of the tongue and cheek, and isolating the quadrants for the clinician. The retraction and continuous suction functions provide the necessary oral environment, reducing contamination and improving bond strength while protecting the airway and soft tissue.

Contraindications

There are no known contraindications. Do not use without reviewing how to select the correct Mouthpiece size for each patient. Do not use if unable to position the Mouthpiece correctly.

Side Effects

Use of the Mouthpiece may trigger a pharyngeal reflex (laryngeal spasm) in hypersensitive patients or if it is not placed correctly within the oral cavity. Contact Zyris for additional placement information if needed.

How Supplied

Isolite 3 System contains: Control Head Hose, Power Vacuum Base, six Vacuum Light Pipes, two Power Supply Options, Accessory Kit and Instructions for Use. Accessories: Cleaning Tip, 6” (trim to length) Vacuum Connector Hose, Double End Tube Brush, and Control Head Hose O-Ring Maintenance Kit.

Mouthpieces

Mouthpieces come in convenient 10-pack boxes. Each non-sterile Mouthpiece is individually packaged in a polyethylene bag. Mouthpieces come in six different sizes for varying patient needs. See Figure 3.

INSTALLATION

Isolite 3 was designed to install easily in most dental operatories. Installation and usage instructions, including a video demonstration, are also available at zyris.com/success.

Step 1
Attach the end of the vacuum connector hose to the chair suction port.

Step 2
Place the Control Head Hose on an empty slot on the tool bar.

Step 3
Connect the Power Vacuum Base onto the vacuum connector hose.

Step 4
Plug in the power adapter to a standard 120V wall power source or have a chair technician hardwire using the supplied direct-to-chair connection cable.
Step 5. Plug in the electrical connector to the top of the Power Vacuum Base.

Step 6. Confirm the light on the Power Vacuum Base is solid blue. Refer to “Using the Power Vacuum Base LED Indicator” section in the IFU if the light is not solid blue.

Step 7. Rotate the suction selection dial to the desired setting.

Section 5. Control Head Without Available HVE Port

Step 1. Unscrew the black screw cap from the PVB accessory port.

Step 2. Screw the provided hose barb into the PVB accessory port.

Step 3. Remove existing HVE tubing from the chair suction port.

Step 4. Attach the end of the vacuum connector hose to the chair suction port.

Step 5. Place the Control Head Hose in an empty slot on the tool bar.

Step 6. Connect the Power Vacuum Base onto the vacuum connector hose.

Step 7. Plug in the power adapter to a standard 120V wall power source or have a chair technician hardwire using the supplied direct-to-chair connection cable.

Step 8. Plug in the electrical connector to the top of the Power Vacuum Base.

Step 9. Confirm the light on the Power Vacuum Base is solid blue. Refer to “Using the Power Vacuum Base LED Indicator” section in the IFU if the light is not solid blue.

Step 10. Rotate the suction selection dial to the desired setting.

Step 11. Rotate the dial to “All” to enable suction for the Isolite 3 and an attached HVE.

How to Operate

Using the Dual Vacuum Levers

Dual Vacuum Levers adjust suction intensity in both the upper and lower quadrants. To adjust suction, rotate the levers to the desired suction intensity. To shut off suction, rotate the levers to the most downward position.

Using the Control Head LED Controls

Table 1. Control Head LED Status

<table>
<thead>
<tr>
<th>Operation</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Turn light on</td>
<td>Tap Light Button once</td>
</tr>
<tr>
<td>Set brightness, when on only</td>
<td>Tap Light Button to cycle through levels</td>
</tr>
<tr>
<td>Set color output, when on or off</td>
<td>Tap Color Button to cycle between white and amber</td>
</tr>
<tr>
<td>Turn light off</td>
<td>Press and hold Light Button</td>
</tr>
</tbody>
</table>

Adjust lighting functions by using the two-button light control.

Table 2. Control Head LED Status

<table>
<thead>
<tr>
<th>LED Indicator</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Light Button indicator</td>
<td>Red (Error)</td>
</tr>
<tr>
<td>Light Button indicator</td>
<td>Light output set to level 1 (green)</td>
</tr>
<tr>
<td>Light Button indicator</td>
<td>Light output set to level 2 (yellow)</td>
</tr>
<tr>
<td>Light Button indicator</td>
<td>Light output set to level 3 (red)</td>
</tr>
</tbody>
</table>

The LED Indicator Buttons feature LED indicators that show the status of the control head.

Table 1. Control Head LED Status

<table>
<thead>
<tr>
<th>LED Indicator</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Color Button indicator</td>
<td>White LED set</td>
</tr>
<tr>
<td>Color Button indicator amber</td>
<td>Amber LED set</td>
</tr>
<tr>
<td>Color Button indicator red</td>
<td>Auto shutdown due to over temperature. Device ready to restart when indicated temperature.</td>
</tr>
</tbody>
</table>

Additionally, the Icon Table 4. PVB LED Status

<table>
<thead>
<tr>
<th>Icon</th>
<th>Function</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isolite 3 Only</td>
<td></td>
</tr>
<tr>
<td>Isolite 3 + Accessory</td>
<td></td>
</tr>
<tr>
<td>Accessory Only</td>
<td></td>
</tr>
<tr>
<td>Off</td>
<td></td>
</tr>
</tbody>
</table>

Decreased suction may occur when Isolite 3 and Accessories are both in use.

Using the Power Vacuum Base LED Indicator

Table 3. PVB Icons

<table>
<thead>
<tr>
<th>Status</th>
<th>Color Button indicator</th>
<th>Light Button indicator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Red</td>
<td>Error</td>
<td></td>
</tr>
<tr>
<td>Blue</td>
<td>Power to Power Vacuum Base, Control Head not connected</td>
<td></td>
</tr>
<tr>
<td>Green</td>
<td>Power to Power Vacuum Base, Control Head not connected</td>
<td></td>
</tr>
</tbody>
</table>

Using The Power Vacuum Base LED Indicator

The LED Indicator shows the status of the PVB.

Table 4. PVB LED Status

<table>
<thead>
<tr>
<th>Color Button indicator</th>
<th>Light Button indicator</th>
</tr>
</thead>
<tbody>
<tr>
<td>White LED set</td>
<td>Light output set to level 1 (green)</td>
</tr>
<tr>
<td>Amber LED set</td>
<td>Light output set to level 2 (yellow)</td>
</tr>
<tr>
<td>Auto shutdown due to over temperature. Device ready to restart when indicated temperature.</td>
<td></td>
</tr>
</tbody>
</table>

Decreased suction may occur when Isolite 3 and Accessories are both in use.
Selecting the Mouthpiece
To select the correct Mouthpiece size, measure the patient's interincisal opening using your fingers until the two locking barbs engage. Water may be used to lubricate the inside surface of the Mouthpiece sleeve to ease attachment.

Placing the Mouthpiece
Prior to placing the Mouthpiece within the patient's oral cavity, moisten the Mouthpiece and the patient's lips.

Step 1
Hold the sides of the Control Head with your index finger and thumb. With your other hand, fold the Cheek Shield onto the Tongue Retractor. Gently slide the folded Mouthpiece into the buccal vestibule on the side to receive treatment. Angle the Mouthpiece to allow the lower edge of the Tongue Retractor to move along the buccal edge of the teeth.

Step 2
Move the bite block onto the occlusal surface of the teeth, just distal to the mandibular cuspid. Instruct the patient to "rest gently" on the bite block to secure.

Step 3
Place the Cheek Shield into the buccal vestibule. Move the Isthmus onto the retromolar pad behind the maxillary tuberosity. Adjust the Tongue Retractor in the lingual vestibule as needed. Move the bite block distally to provide more vertical working room.

For additional assistance, watch a video demonstration online at zyris.com.

Table 3. Mouthpiece Sizes

<table>
<thead>
<tr>
<th>Mouthpiece Size</th>
<th>Approx. Interincisal opening</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pediatric (PED)</td>
<td>&lt; 30mm</td>
</tr>
<tr>
<td>Extra Small (XSM)</td>
<td>&lt; 30mm</td>
</tr>
<tr>
<td>Small (SML)</td>
<td>30mm</td>
</tr>
<tr>
<td>Medium (MED)</td>
<td>30–45mm</td>
</tr>
<tr>
<td>Medium Deep Vestibule (MDV)</td>
<td>30–45mm</td>
</tr>
<tr>
<td>Large (LRG)</td>
<td>&gt; 45mm</td>
</tr>
</tbody>
</table>

Selecting the Mouthpiece Size Method
Use your fingers or the Boley Gauge to select the appropriate Mouthpiece size (Figure 3).

Tongue Retractor Gently slide the folded Mouthpiece into the buccal vestibule on the side to receive treatment. Angle the Mouthpiece to allow the lower edge of the Tongue Retractor to move along the buccal edge of the teeth.

Step 2: Move the bite block onto the occlusal surface of the teeth, just distal to the mandibular cuspid. Instruct the patient to "rest gently" on the bite block to secure.

Step 3: Place the Cheek Shield into the buccal vestibule. Move the Isthmus onto the retromolar pad behind the maxillary tuberosity. Adjust the Tongue Retractor in the lingual vestibule as needed. Move the bite block distally to provide more vertical working room.

Surface Disinfection of the Control Head Hose
Zyris recommends performing a surface disinfection of the Control Head Hose between each patient. To disinfect the Control Head Hose, first remove the Vacuum Light Pipe.

Following the manufacturer's instructions, for contact time, use an intermediate level disinfectant wipe with a claim to inactivate Mycobacterium tuberculosis. Otherwise, use a hospital grade disinfectant on all surfaces of the Control Head and the Control Head Hose to remove all visible biomatter and debris.

Do not submerge the Control Head Hose.
should be turned off to remove dial for maintenance or open the HVE tip to relieve the suction from the dial.

WARNINGS

**WARNING:** Shock hazard if incorrect power supply is used. Only use the power supplies provided with your Isolite 3 device. Use of other power sources may damage electronics and voids your product warranty. The Power Vacuum Base power input requirement is 12 VDC / 24VAC, 1.0 amp.

**WARNING:** Mouthpieces are single use only. Re-use can result in the transmission of infectious pathogens. Mouthpieces must be discarded after use.

Zyris recommends sterilization of the Isolite 3 Vacuum Light Pipe between each patient. Mouthpieces cannot be safely resterilized after use. **WARNING:** Do not use if the individual Mouthpiece package has been damaged or opened. **WARNING:** Be sure to use established protocols and patient monitoring when using the Mouthpiece in conjunction with sedation dentistry. Patient management by a certified anesthesiologist is strongly recommended.

### Table 4. Validated Sterilization Cycles

<table>
<thead>
<tr>
<th>Cycle</th>
<th>Temperature</th>
<th>Minimum Exposure Time</th>
<th>Minimum Drying Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard</td>
<td>121 ºC / 250 ºF</td>
<td>30 min</td>
<td>30 min</td>
</tr>
<tr>
<td>Standard</td>
<td>126 ºC / 259 ºF</td>
<td>10 min</td>
<td>30 min</td>
</tr>
<tr>
<td>Standard</td>
<td>132 ºC / 270 ºF</td>
<td>15 min</td>
<td>15 min</td>
</tr>
<tr>
<td>Prevacuum</td>
<td>132 ºC / 270 ºF</td>
<td>4 min</td>
<td>20 min</td>
</tr>
<tr>
<td>Prevacuum</td>
<td>134 ºC / 273 ºF</td>
<td>3 min</td>
<td>20 min</td>
</tr>
</tbody>
</table>

Remove biomatter and other debris from the suction channels using a brush with a neutral pH (6.5-7.5) enzymatic cleaning solution. Do not use solution to hold parts. After cleaning, rinse with tap water, dry and place components in an autoclave pouch to be sterilized in a steam autoclave. Use validated sterilization cycles (Table 4).

### MAINTENANCE

**Control Head Hose and Power Vacuum Base Internal Surfaces**

Cleaning the inside of the Control Head Hose and Power Vacuum Base is required to prevent the accumulation of debris. To clean the inside of the Control Head Hose and Power Vacuum Base, first remove the VLP, attach and connect the Cleaning Tip to the Control Head. Next, attach the Control Head Hose to the orifice of the power vacuum base. Actuate the suction by drawing the dental hose cleaner through the hose per the manufacturer’s instructions. The vacuum hose cleaner should be nonfoaming, deodorizing, antimicrobial, and able to dissolve organic debris. Most enzymatic cleaners are acceptable. If further disinfection is necessary, consult your vacuum manufacturer for recommendations. When complete, remove the Cleaning Tip and place in an autoclave bag for storage until the next cleaning.

**Control Head Hose Levers**

The Vacuum Lever o-rings require weekly lubrication to operate at peak efficiency. Before removing the levers, rotate the dial on the Power Vacuum Base to the “X” to shut off the suction. To remove the Vacuum Lever, push the levers to the “on” position and keep pushing gently until each lever pops out or gently pry them out. Apply Dow 111 Lubricant supplied in the O-Ring Maintenance Kit to the o-ring. Reattach the Vacuum Levers to the Control Head Hose.

**Power Vacuum Base**

The Power Vacuum Base dial may require lubrication, depending on the frequency of use. To remove the dial, rotate clockwise past the “X” position to the eject “   ” position and pull it out of the Power Vacuum Base. Apply Dow 111 Lubricant supplied in the O-Ring Maintenance Kit to the dial. To re-insert the dial, rotate clockwise past the “X” position to the eject “   ” position and pull it out of the Power Vacuum Base. The central suction system should be turned off to reboot for maintenance or open the HVE Tip to relieve the suction from the dial.

**WARNING:** Shock hazard if incorrect power supply is used. Only use the power supplies provided with your Isolite 3 device. Use of other power sources may damage electronics and voids your product warranty. The Power Vacuum Base dial o-ring may require lubrication, depending on the frequency of use. To remove the dial, rotate clockwise past the “X” position to the eject “   ” position and pull it out of the Power Vacuum Base. Apply Dow 111 Lubricant supplied in the O-Ring Maintenance Kit to the o-ring. Re-insert the dial to the Power Vacuum Base. The central suction system should be turned off to reboot for maintenance or open the HVE Tip to relieve the suction from the dial.

**WARNING:** Do not discard after use. Mouthpieces cannot be safely resterilized after use.

**WARNING:** Do not use if the Mouthpiece package has been damaged or opened.

**WARNING:** Be sure to use established protocols and patient monitoring when using the Mouthpiece in conjunction with sedation dentistry. Patient management by a certified anesthesiologist is strongly recommended.
CAUTION: When performing dental procedures requiring high levels of blood evacuation, it is recommended that the Mouthpiece be intermittently flushed with water to prevent coagulation in the Mouthpiece to avoid loss of suction and light transmission.

CAUTION: With regular use, cleaning, and maintenance, the device is designed to last for years. Check the device for wear prior to use to make sure that it is adequate for use.

CAUTION: Do not block access to the Power Adapter. The Power Adapter should be easily accessible so that it can be unplugged from the wall outlet if necessary.

CAUTION: To avoid electrical shock, the use of an extension cord with the Power Adapter is not recommended.

CAUTION: Do not crimp or fold the Power Hose to shut off suction. Internal damage to the Power Hose may occur.

CAUTION: The Control Head Hose and Power Vacuum Base contain sensitive electronics and require special care and handling. Do not submerge, autoclave, chemclave or place in ultrasonic cleaner.

CAUTION: Do not autoclave the Vacuum Light Pipe at temperatures above 135 °C; higher temperatures could damage components and void your product warranty.

CAUTION: Do not hold Control Head Hose or Power Vacuum Base in cleaning solution or use ultrasonic cleaners.

CAUTION: Failure to maintain properly lubricated o-rings can result in damage to the Isolite 3 device that is not covered by the manufacturer’s warranty. Zyris recommends that you follow a strict maintenance protocol to keep your Isolite 3 device in top condition.

CAUTION: Do not re-use this product. Consult Instructions for Use before using this product.

CAUTION: Positive polarity Type B applied part electrical hazard

GUIDE TO SYMBOLS

Zyris warrants this product to be free from defects in material and workmanship for a period of one year from the date of original purchase. If the product exhibits such a defect, Zyris will, at its option, repair or replace it without costs for parts and labor. The product must be returned by the customer to Zyris in accordance with current Return Material Authorization procedures. Proof of date of original purchase may be required.

This warranty does not cover finishes or normal wear, nor does it cover damage resulting from accident, misuse, dirt, tampering, unreasonable use, failure to provide reasonable and necessary maintenance, service performed or attempted by unauthorized individuals or service agencies, or devices that have been otherwise modified. All implied warranties, including any implied warranty or merchantability or fitness for any particular purpose, are limited in duration to one year from the date of receipt of the product. In no event will Zyris be responsible for consequential damages resulting from the use of this product.

Zyris would like your help improving the quality of our products by automatically collecting and sending anonymous usage data from your Isolite 3 to Zyris. Usage data collected includes internal temperature, device position, light color, and light level. No patient or account information is recorded or transmitted. Zyris does not share this information with any third parties under any circumstances. If you would prefer to opt-out of sending usage data Professional device, please visit Zyris.com/i3-optout.

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