

VALIDATED AUTOCLAVE CYCLES

Cycle	Temperature	Minimum Exposure Time	Minimum Drying Time
Standard	121 °C / 250 °F	30 min	30 min
Standard	126 °C / 259 °F	10 min	30 min
Standard	132 °C / 270 °F	15 min	15 min
Prevacuum/SFPP	132 °C / 270 °F	4 min	20 min
Prevacuum/SFPP	134 °C / 273 °F	3 min	20 min





CONTRAINDICATIONS

No known contraindications. Do not use without reviewing how to select the correct Zyris Isolite® Anterior/Posterior Mouthpiece size for each patient. Do not use if unable to position the mouthpiece correctly.

SIDE EFFECTS

Use of our 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.











WARNINGS

- **WARNING:** Zyris Isolite® Mouthpieces are single-use only. Reuse can result in the transmission of infectious pathogens. Mouthpieces must be discarded after use. Mouthpieces cannot be safely sterilized after use.
- **WARNING:** Do not use if the individual mouthpiece package has been previously damaged or opened. Non-sterile mouthpieces are individually packaged in polyethylene bags.
- **WARNING:** Be sure to use established protocols and patient monitoring when using our mouthpieces in conjunction with sedation dentistry. Patient management by a certified anesthesiologist is strongly recommended.
- **WARNING:** Shock hazard if incorrect power supply is used. Only use the power supply provided with your Zyris Isolite Pro system. Use of other power sources may damage electronics and voids your product warranty. The Power Vacuum Base power input requirement is 12 VDC, 1.0 amp.

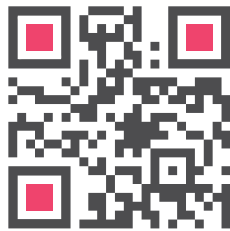
DATA COLLECTION

To learn more and opt out, go to Zyris.com/i3-optout.

PRECAUTIONS

- **CAUTION:** When performing dental procedures requiring high levels of blood evacuation, it is recommended that our mouthpieces be intermittently flushed with water. This prevents coagulation in the mouthpiece, avoiding 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 Supply. The Power Supply 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 Supply is not recommended.
- **CAUTION:** Do not crimp or fold the Control Head Hose to shut off suction. Internal damage to the Control Head Hose wiring 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 any components 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 Zyris Isolite Pro device that is not covered by product warranty.
- **CAUTION:** This device complies with Part 15 of the FCC rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Video instructions can be found at:



<https://zyr.is/proifu>



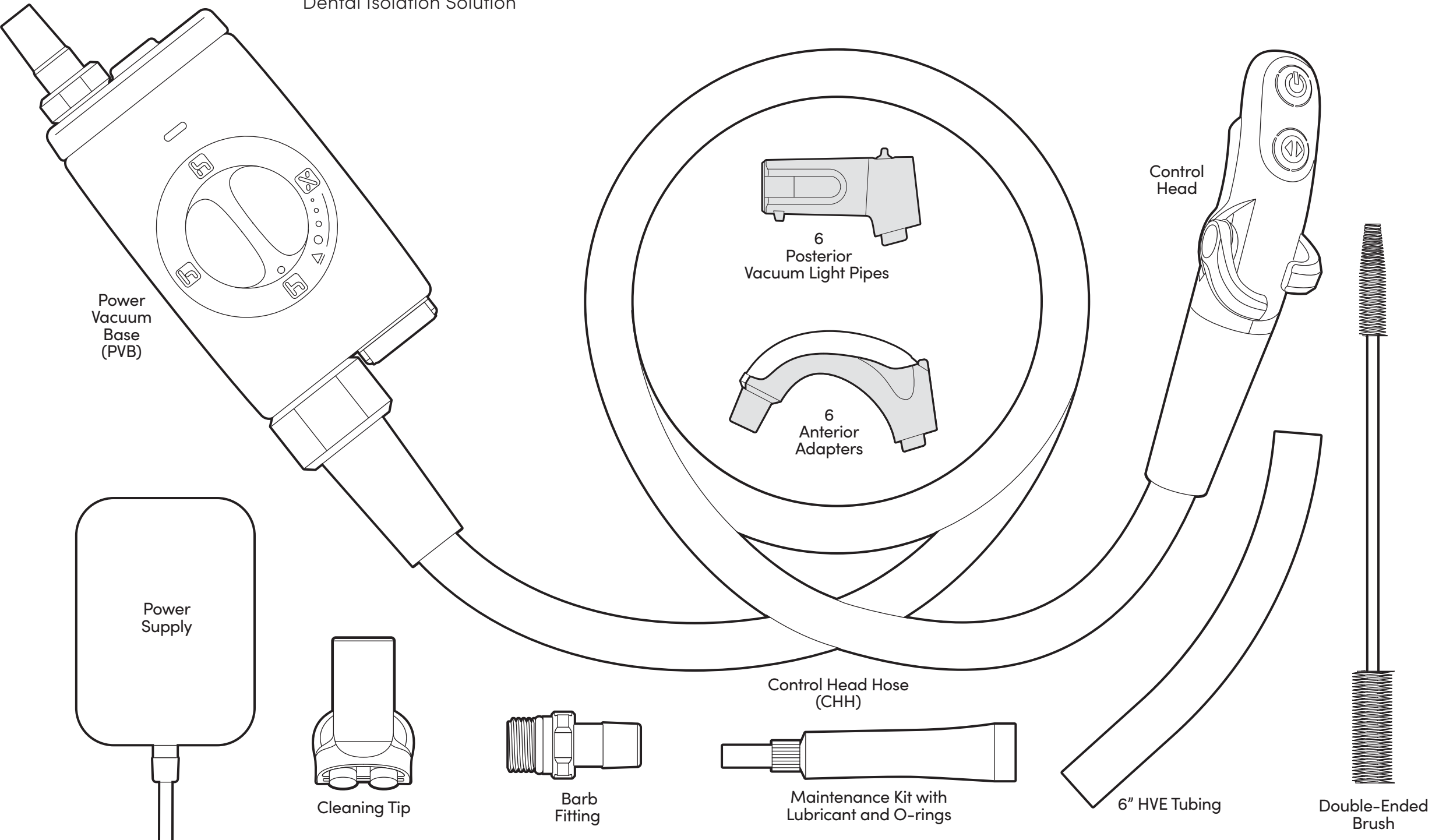
Limited 1-Year Warranty
<https://www.zyris.com/warranty>

ZYRIS®

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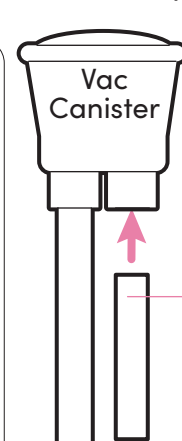
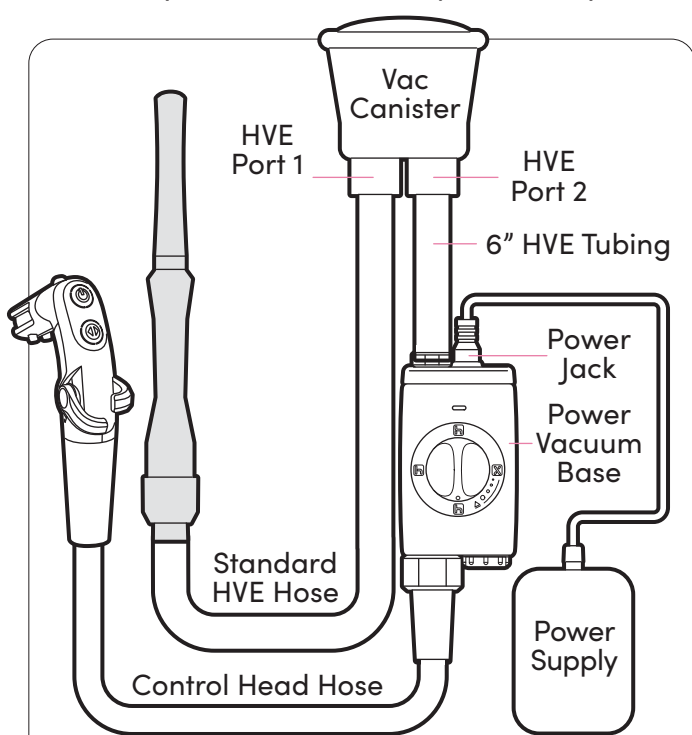
ZYRIS® **isolite®**
pro

Illuminated Whole Mouth
Dental Isolation Solution



INSTRUCTIONS FOR USE

Installation Instructions Determine the HVE connection technique for Zyris Isolite Pro.
NOTE: If you do not have an open slot on your toolbar, contact your distributor.



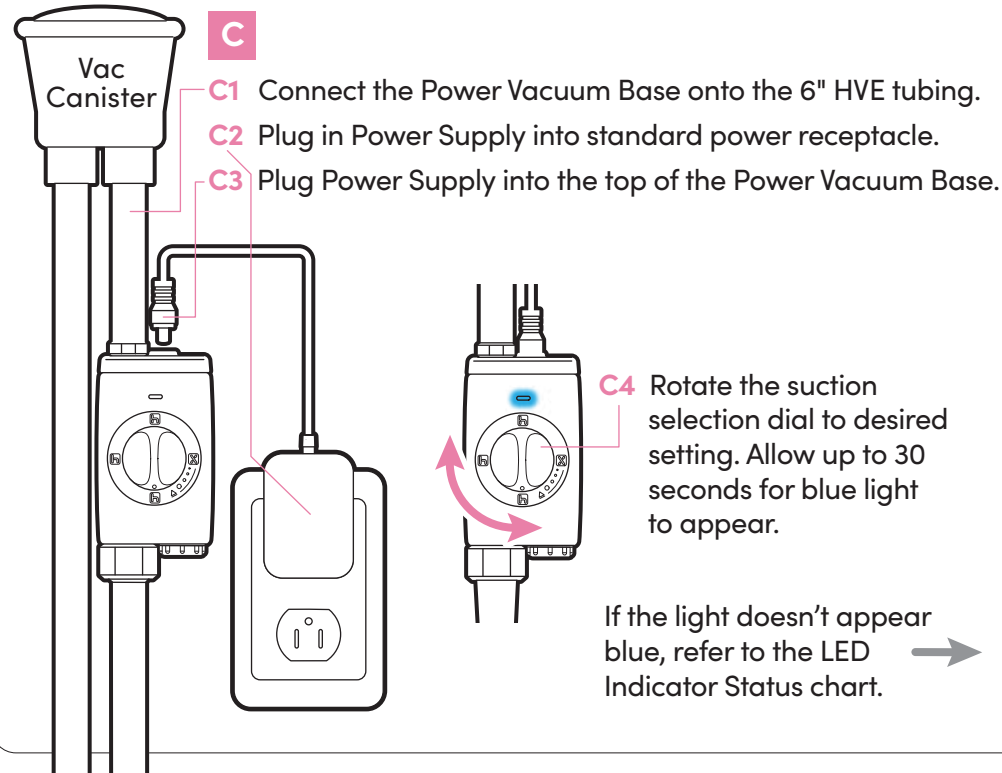
- A Direct connection** to open port on vacuum canister.
- A1** Connect the 6" HVE tubing to the open port on the vacuum canister. (Trim to desired length.)
- TIP:** If tubing is difficult to connect to vacuum canister port, soak tube end in hot water a few minutes to make it more pliable.
- A2** Place the control head onto an empty slot on the toolbar. Proceed to Step C.

If your HVE tubing does not fit our supplied barb adapter, please go to our connections webpage for more information on connecting your system at zyr.is/connection.

OR B No open ports on vacuum canister installation.

- B1** Place the control head on to an empty slot on the toolbar.
- B2** Remove accessory cap from Power Vacuum Base and attach the barb fitting in its place.
- B3** Remove your current HVE hose from the HVE port and attach to the barb fitting.
- B4** Connect the 6" HVE tubing to the open port on the vacuum canister. (Trim to desired length.) Proceed to Step C.

NOTE: Customer's HVE

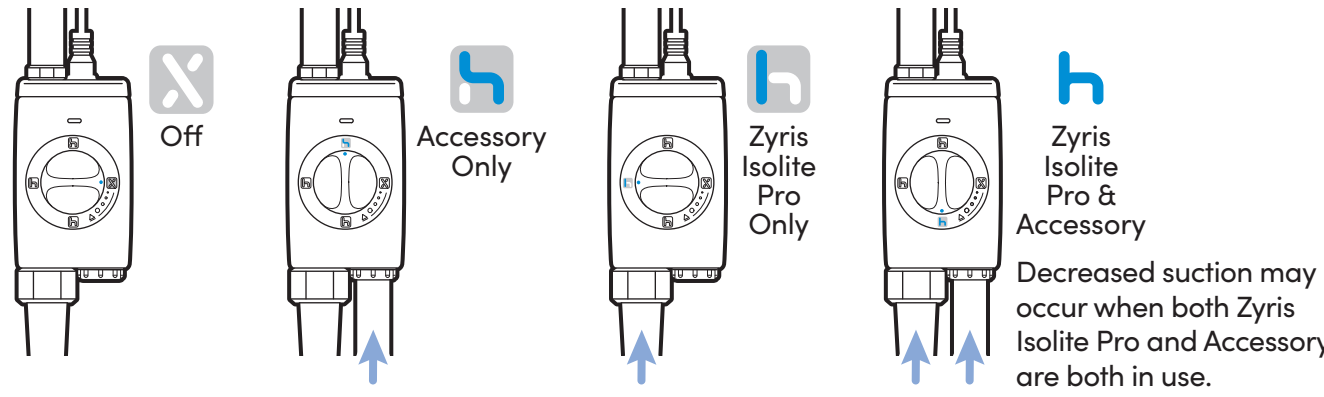


- C**
- C1** Connect the Power Vacuum Base onto the 6" HVE tubing.
- C2** Plug in Power Supply into standard power receptacle.
- C3** Plug Power Supply into the top of the Power Vacuum Base.
- C4** Rotate the suction selection dial to desired setting. Allow up to 30 seconds for blue light to appear.

If the light doesn't appear blue, refer to the LED Indicator Status chart.

Power Vacuum Base Operation Instructions

How to control your Power Vacuum Base. The PVB has a three-way valve to adjust suction for your specific chair configuration.



LED Indicator	Status
Red	Error - Repeat step C3. If still red, contact support.
Blue	Power to Power Vacuum Base Control Head Hose connected.
Green	Power to Power Vacuum Base Control Head Hose not connected.

Intended Use

In one system, the Illuminated Dental Isolation System allows you to perform Anterior/Posterior procedures quickly and easily for consistent outcomes. Utilizing the Isolite family of mouthpieces you can experience the following:

- Retraction for better visibility
- Effective isolation
- Continuous suction for moisture control and aerosol/spatter reduction
- Airway protection
- Bite block for patient comfort and safety
- Reduced patient chair time

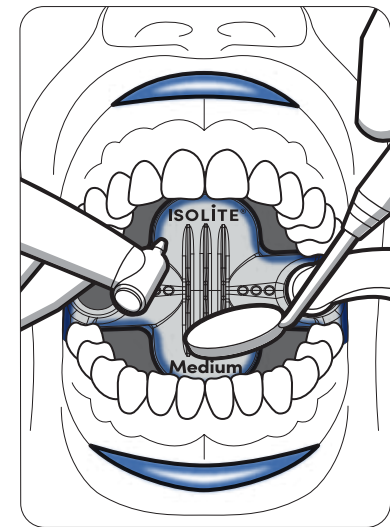
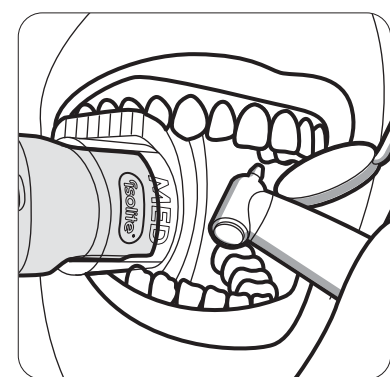
Depending on procedure needs, determine which Zyris Isolite® Mouthpiece will work best.

For posterior or quadrant-based procedures that need intraoral illumination, connect the Posterior Vacuum Light Pipe to Control Head with our posterior mouthpiece.

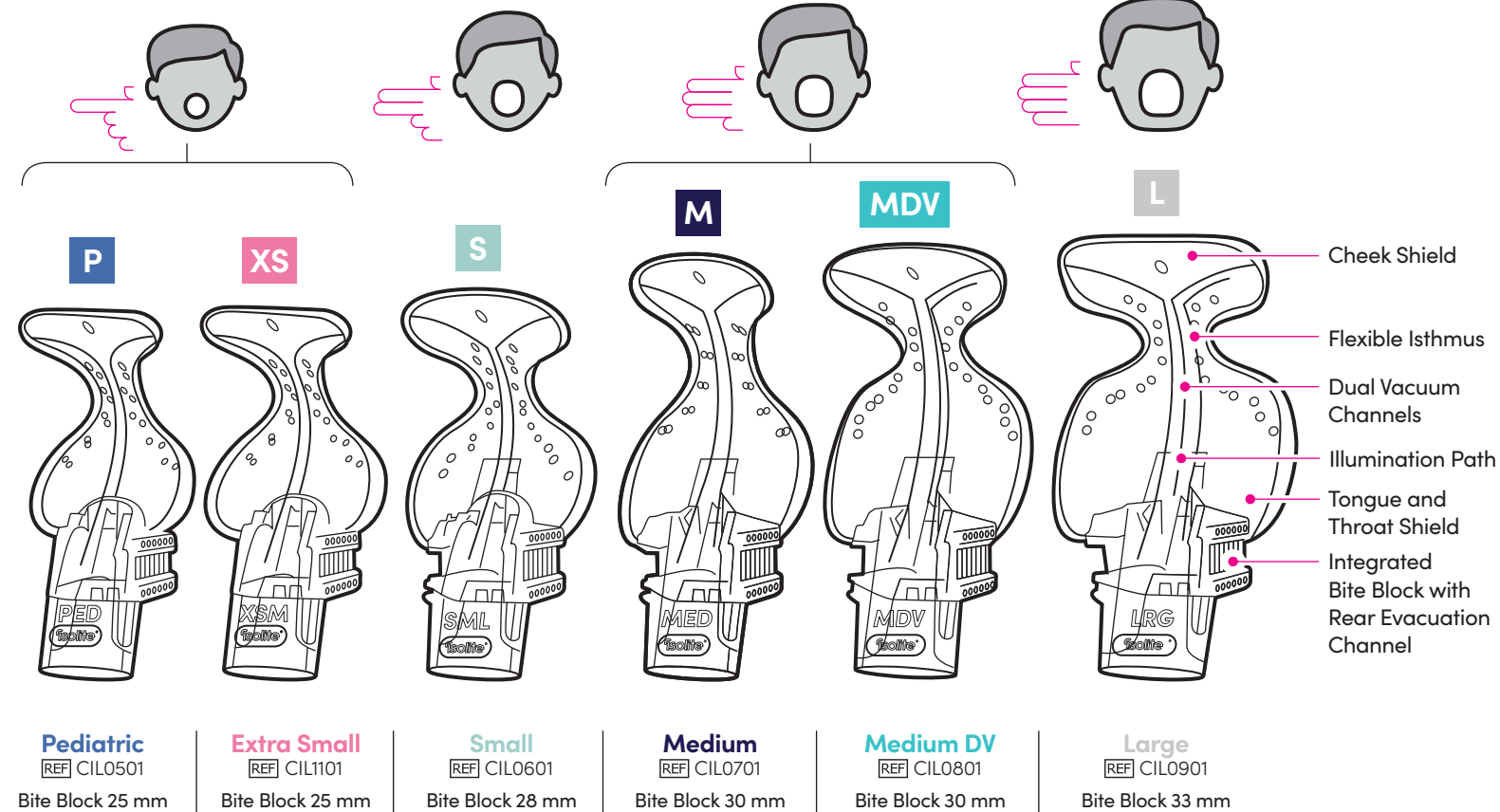
See "Posterior Procedures" in next steps.

For anterior or premolar to premolar procedures, connect the Anterior Adapter to the Control Head with our anterior mouthpiece.

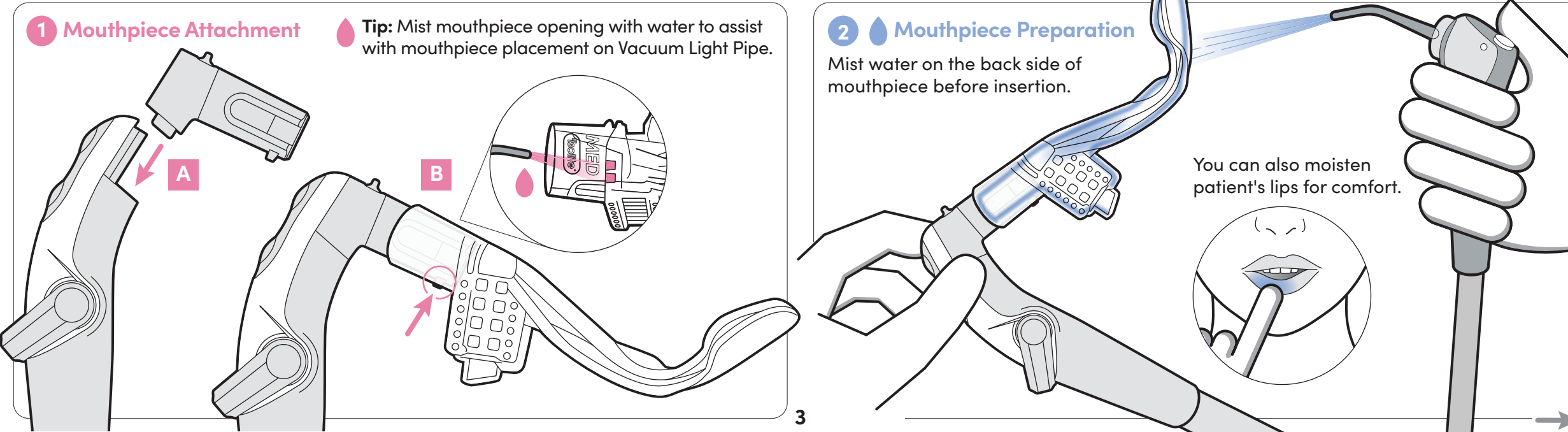
See "Anterior Procedures" steps starting on page 5.



Zyris Isolite Posterior Mouthpieces Sold Separately



Posterior Procedures



3
Mouthpiece Insertion

4
Mouthpiece Insertion

Insert into cheek.

5
Operation Instructions

Dual Vacuum Levers adjust suction in both the upper and lower quadrants.

To adjust, rotate the left and right Vacuum Levers to the desired suction level for each quadrant.

To shut off suction, rotate the levers to the downward position.

8
Intended Use

9
Cleaning and Disinfection

Cleaning and Autoclaving of Vacuum Light Pipe

Zyris recommends cleaning and autoclaving of the Vacuum Light Pipe promptly after each patient use.

To clean the Vacuum Light Pipe, use brush with a pH neutral enzymatic cleaning solution to remove all visible biomatter until visibly clean.

Rinse with water, dry and place components in autoclave pouch. Use validated autoclave cycles.

Surface Disinfection of 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 Control Head Hose.

6
Using the Control Head LED Controls

A
ON: Tap top power button once.

OFF: Press and hold top power button until light turns off.

B
Tap top button to control your three light settings.

LED Indicator	Status
Light Button indicator LEDs 1, 2 & 3	Light output set to level 1, 2 or 3
Light Button indicator LEDs pulse	Self-regulating temperature control has automatically lowered the brightness to reduce heat output

7
How to control your two light color settings.

LED Indicator	Status
Color Button Indicator White	White LED set
Color Button Indicator Amber	Amber LED set

Zyris Isolite® Anterior Mouthpieces (Sold Separately)

P

S

M

L

Young children (2-7) and adults with very small arches or limited lip elasticity

Children and adults with narrow or V-shaped arches

Larger children and adults with average or U-shaped arches

Adults with very wide arches

- Lip Retractor
- Frenum Divot
- Throat Protection
- Suction Holes
- Suction Port
- Tongue Retraction

Anterior Procedures

1 Mouthpiece Attachment **A**

Insert adapter into preferred side of mouthpiece. Press adapter firmly into place.

Tip: Mist mouthpiece opening with water to assist with mouthpiece placement on adapter.

B

1. Spray water into non-working side suction port.
2. Hold back side of suction port and push adapter in all the way.

Note: Do not turn on light when using the Anterior Mouthpieces.

6 Intended Use

A Single-use only, do not reuse.

Tip: Wet mouthpiece prior to removal for patient comfort.

Dispose of in accordance with federal, state, and local laws after use. Do not autoclave.

Suction level can be adjusted as needed to reduce noise and overdrying of patient tissue.

B

2 Mouthpiece Preparation

Mist water on the mouthpiece before insertion. You can also moisten patient's lips for comfort.

3 Mouthpiece Insertion

Hold device in one hand, and fold mouthpiece with your other hand.

4 Mouthpiece Insertion

Insert at an angle toward the cheek, by placing one corner of the bite block into the patient's mouth near the patient's first molar.

A **B** **C** Once one side is in, keep mouthpiece compressed and place other side on the first molar.

5 Mouthpiece Insertion

Have the patient bite down on bite block to keep in place and using your fingers, sweep around the mouthpiece to secure it in the vestibule.

Adjust bite block slightly forward or back or rotate slightly to improve access and comfort.

ISOLITE
Medium

7 Cleaning and Disinfection of Anterior Adapter

Zyris recommends cleaning and autoclaving of the anterior adapter promptly after each patient use. Separate adapter into two pieces by applying pressure at the seam as indicated below. The tab is designed to assist in removing the adapter from the Zyris Isolite Pro. Use brush with pH neutral enzymatic solution to remove all visible biomatter until visibly clean. Rinse with water, dry and place components in an autoclave pouch. Use validated autoclave cycles.

Note: Do not pull on the tab or the adapter may break.

A **B** **C**

Surface Disinfection of Control Head Hose and Power Vacuum Base

Zyris recommends performing a surface disinfection of the Control Head Hose and Power Vacuum Base between each patient. To disinfect the Control Head Hose and Power Vacuum Base, first remove the anterior adapter. 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 Control Head Hose or Power Vacuum Base.

Daily Maintenance

Control Head Hose and Power Vacuum Base Internal Surfaces

Zyris recommends cleaning the inside surfaces of the Control Head Hose and Power Vacuum Base daily to prevent accumulation of biofilm. To thoroughly rinse the inside surfaces of the Power Vacuum Base, turn dial through all the settings while running cleaning fluid through system.

A Attach Cleaning Tip

B Connect to Portable or Chairside Cleaning Canister

Do not submerge Control Head Hose in a cleaning solution bucket. You can insert a standard HVE tip into the cleaning tip to suction solution without submerging control head.

C Turn on Levers

D Pull air through the hose for at least the last 30 seconds to ensure complete drying. Turn off levers

E Remove Cleaning Tip and place in an autoclave pouch for storage until the next cleaning

Note: Hose cleaner should be nonfoaming, deodorizing, antimicrobial, and able to dissolve organic debris. Follow hose cleaner manufacturer's instructions. If further disinfection is needed, consult your vacuum manufacturer for recommendations. At a minimum, open and close valves daily, to keep hose dry from other suction devices connected to the same suction canister.

Weekly Maintenance

Zyris recommends cleaning and maintaining the Control Head Hose and Power Vacuum Base weekly.

1 Cleaning and Maintenance of the Control Head Hose

A Turn Power Vacuum Base dial to the off position ("X").

B Push levers to "on" position and keep pushing gently until they pop off.

C Use brush to clean levers and lever bore thoroughly. Rinse levers with water.

D When levers become tight, apply provided lubricant to vacuum lever o-rings.

E Match • (Left) and •• (Right) inside of lever to match on Control Head Hose for placement.

A OFF **B** ON **C** **D**

2 Cleaning and Maintenance of the Power Vacuum Base

The **Power Vacuum Base** dial may require cleaning, depending on the frequency of use.

A Turn off vacuum supply and unplug Power Vacuum Base.

B To remove the dial, rotate past the "X" position to the "Δ" (Eject) position.

C Pull dial out of the Power Vacuum Base and use brush to clean thoroughly.

D Apply provided lubricant to interior surfaces of the Power Vacuum Base and dial's o-ring and face seal.

A **B** **C** **D**

Return dial to installed position in Power Vacuum Base.