

VALIDATED STERILIZATION 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.

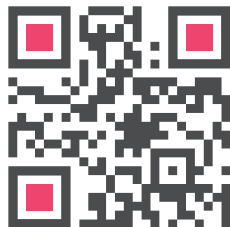
DATA COLLECTION

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>

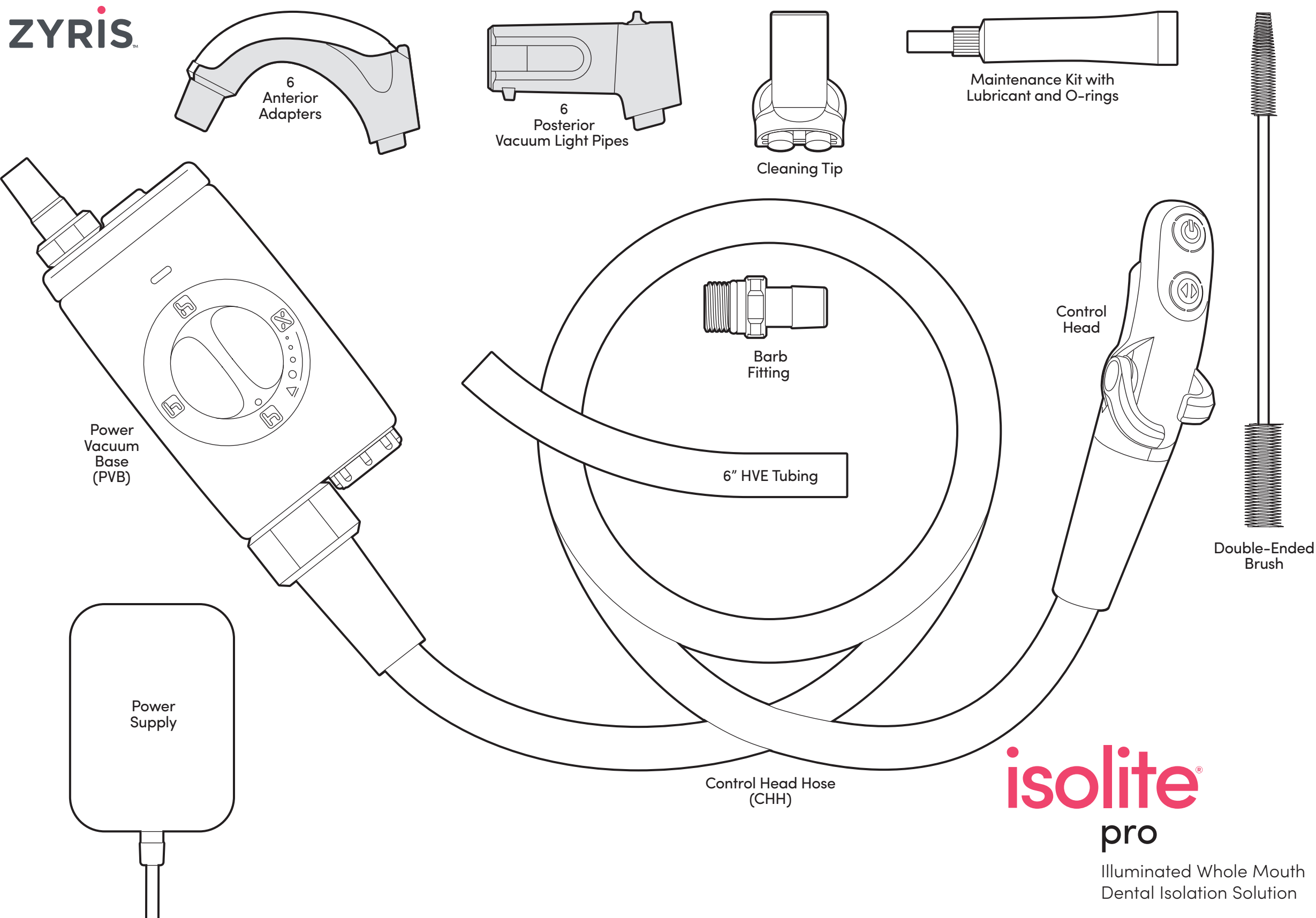


Limited 1-Year Warranty
<https://www.zyris.com/warranty>

ZYRIS™

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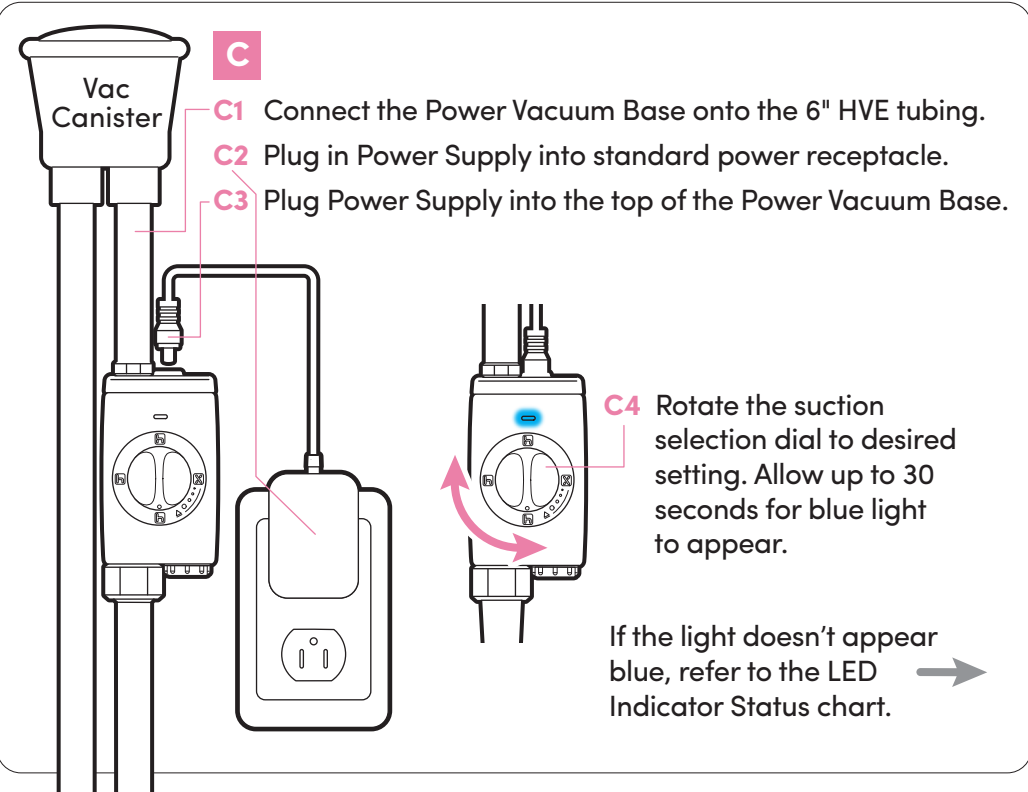
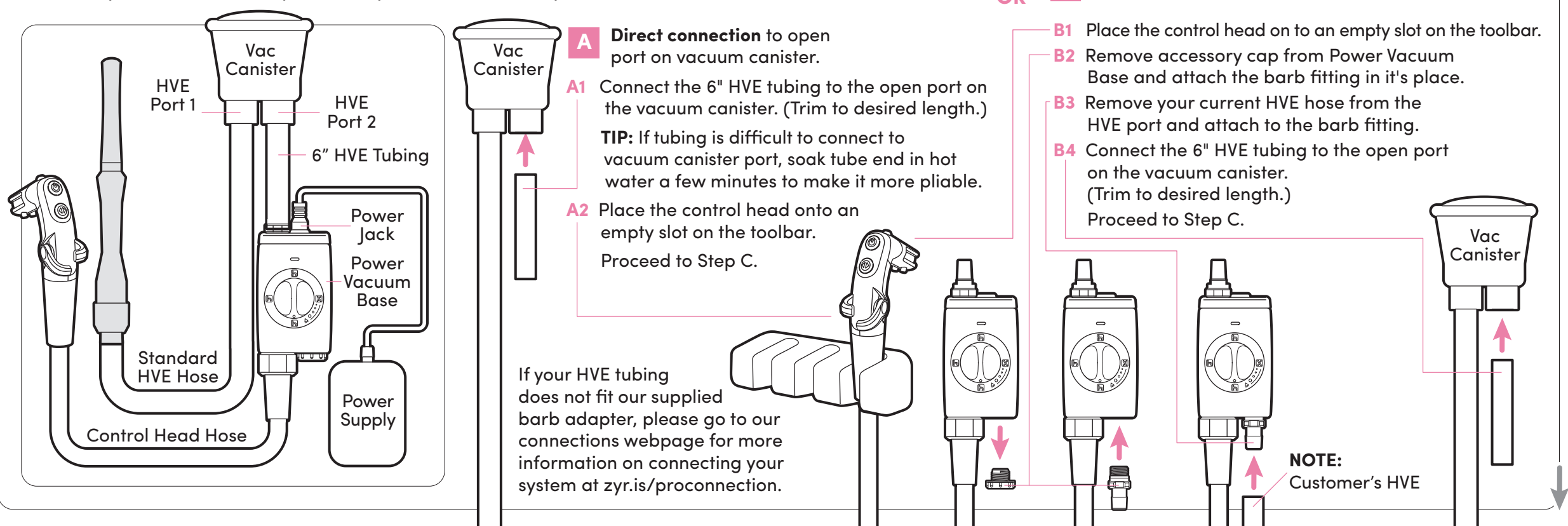
ZYRIS™



isolite®
pro

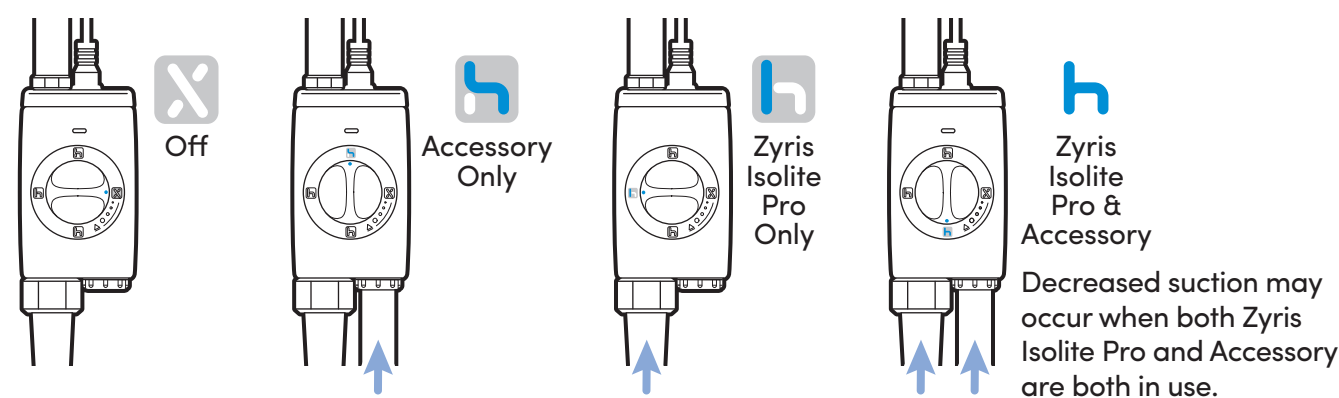
Illuminated Whole Mouth
Dental Isolation Solution

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.



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.

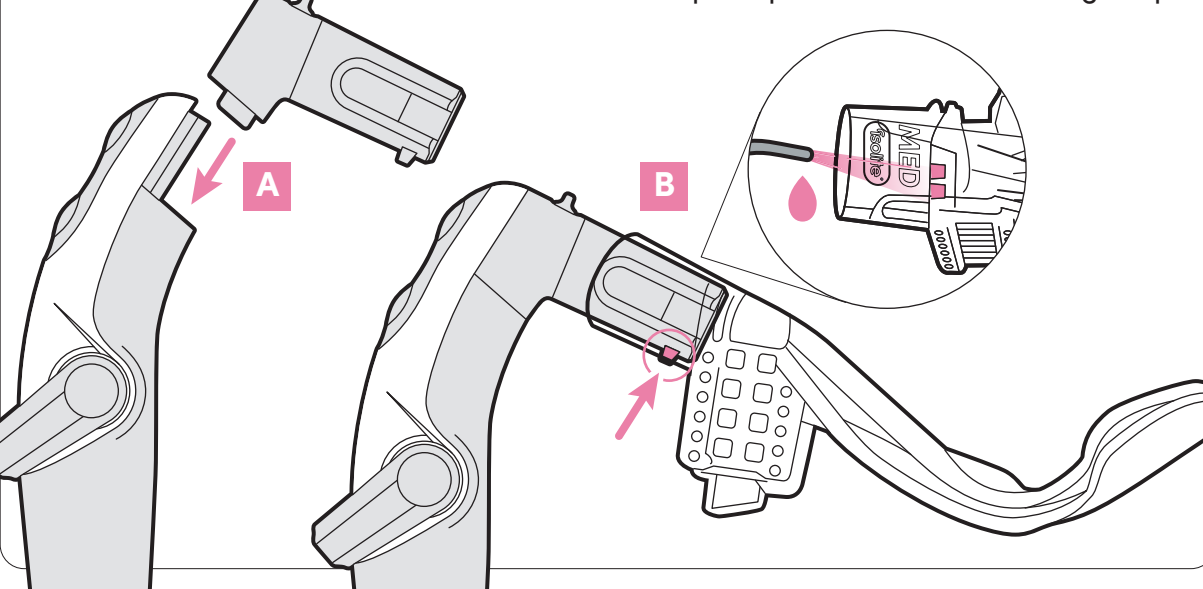
For anterior or premolar to premolar procedures, connect the Anterior Adapter to the Control Head with our anterior mouthpiece.

See "Anterior Procedures" steps starting on page 5.

Posterior Procedures

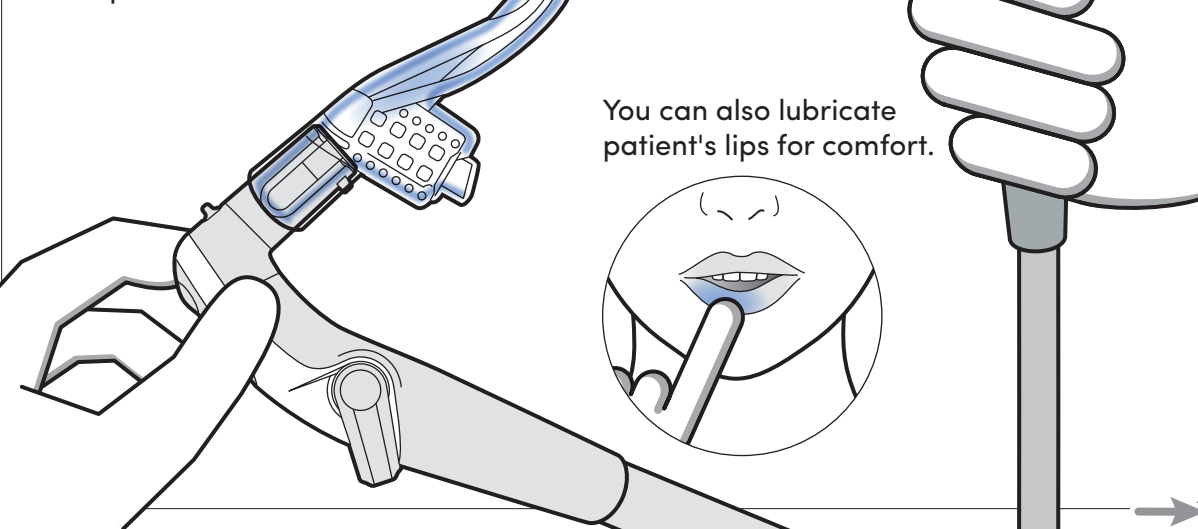
1 Mouthpiece Attachment

Tip: Mist mouthpiece opening with water to assist with mouthpiece placement on Vacuum Light Pipe.

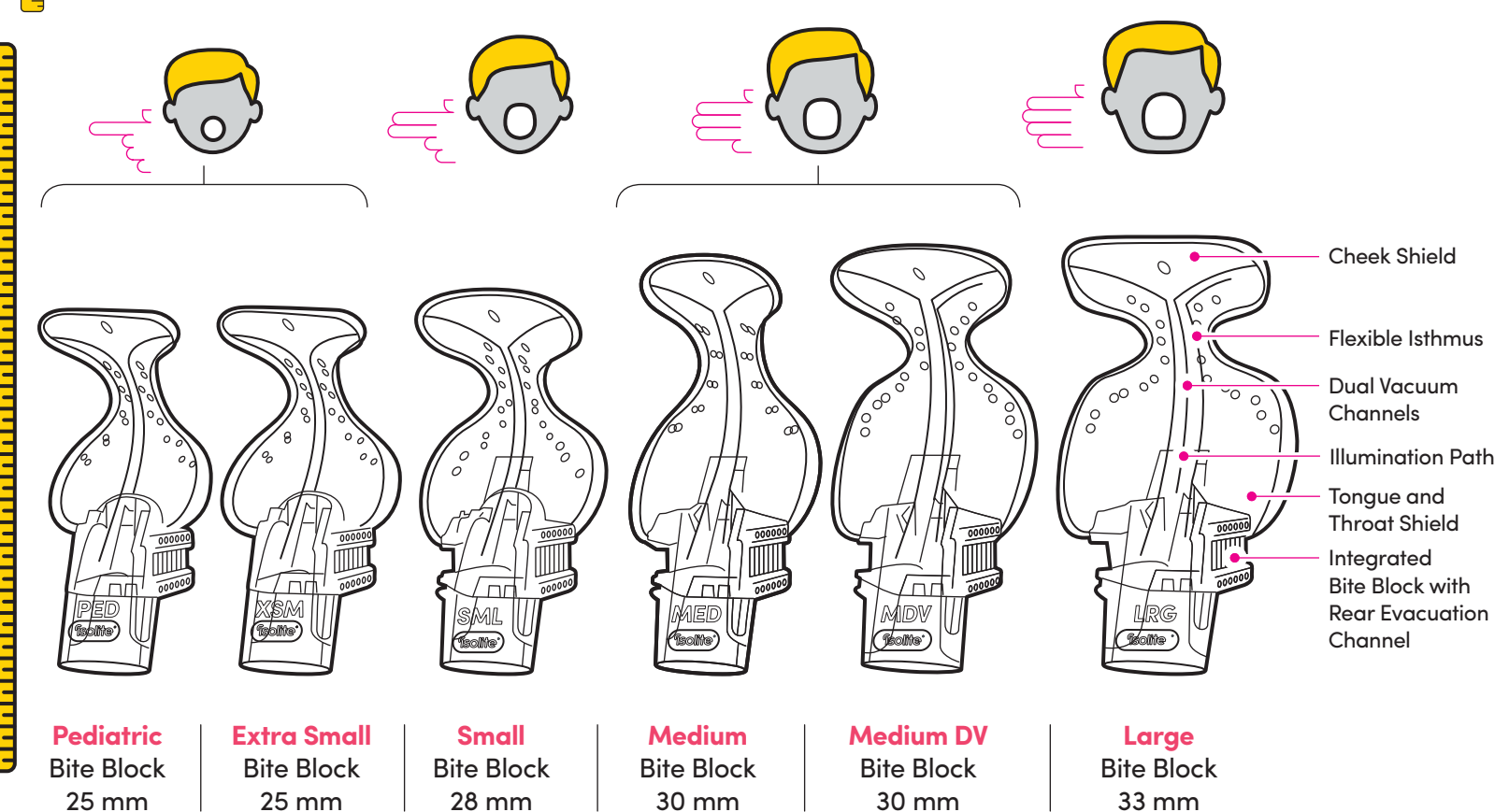


2 Mouthpiece Lubrication

Mist water on the back side of mouthpiece before insertion.



Zyris Isolite Posterior Mouthpieces Sold Separately



3
Mouthpiece Insertion

4
Mouthpiece Insertion

Insert into cheek.

Drag across midline and have patient bite.

The bite block can be moved forward or backward or rotated as needed for access and comfort.

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, Disinfection and Sterilization

Cleaning and Sterilization of Vacuum Light Pipe

Zyris recommends cleaning and sterilization of the Vacuum Light Pipe after each patient use.
To clean the Vacuum Light Pipe, use brush with enzymatic cleaning solution to remove all visible biomatter.
Rinse with water and place components in autoclave pouch to be sterilized. Use validated sterilization 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

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

S

Children and adults with narrow or V-shaped arches

M

Larger children and adults with average or U-shaped arches

L

Adults with very wide arches

Anterior Procedures

1 Mouthpiece Attachment

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.

2 Mouthpiece Lubrication

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

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

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.

5 Mouthpiece Insertion

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

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

6 Intended Use

Single-use only, do not reuse.

Tip: Wet mouthpiece prior to removal for patient comfort.

7 Cleaning and Sterilization of Anterior Adapter

Zyris recommends cleaning and sterilization of the anterior adapter 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 enzymatic cleaning solution to remove all visible biomatter. Rinse with water and place components in an autoclave pouch to be sterilized. Use validated sterilization cycles.

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

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.

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 lubricating the Control Head Hose and Power Vacuum Base weekly.

1 Cleaning and Lubrication 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 Apply provided lubricant to vacuum lever o-rings.

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

2 Cleaning and Lubrication 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.

Return dial to installed position in Power Vacuum Base.