### **VALIDATED AUTOCLAVE CYCLES**

Cycle	Temperature	Minimum Exposure Time	Minimum Drying Time
Standard	121 ºC / 250 ºF	30 min	30 min
Standard	126 ºC / 259 ºF	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 ºC / 273 ºF	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.
- (S) WARNING: Do not use if the individual mouthpiece package has been previously damaged or opened. Non-sterile mouthpieces are individually packaged in polyethylene bags.
- **MARNING:** 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 submerse, 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



recyclable paperboard

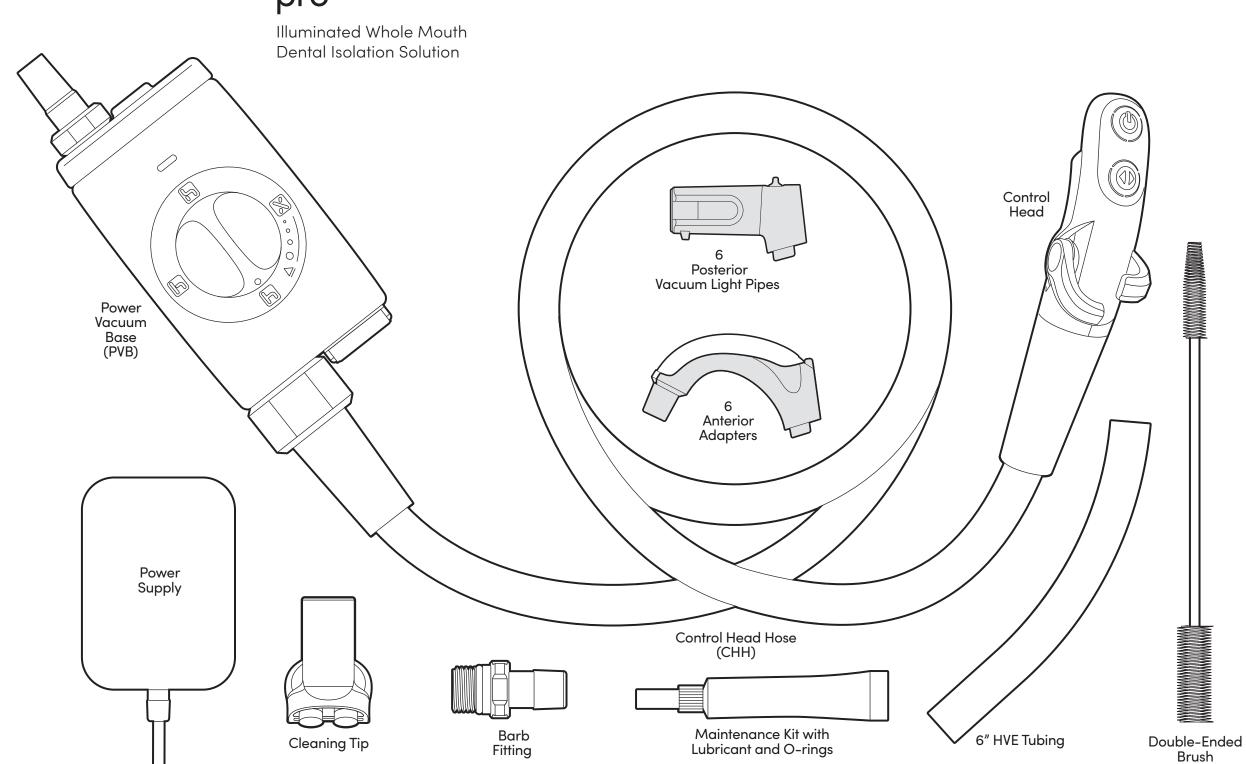
**Limited 1-Year Warranty** https://www.zyris.com/warranty

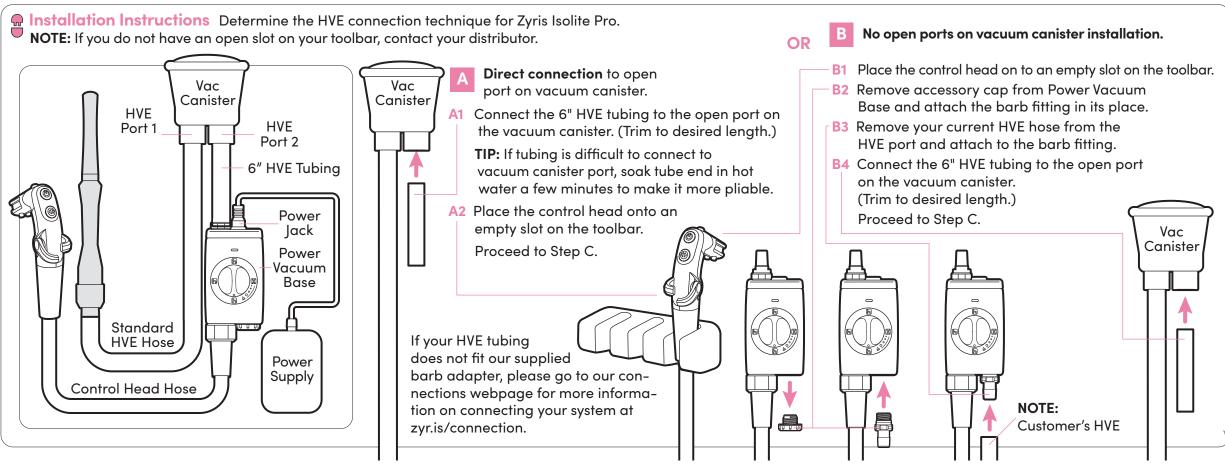


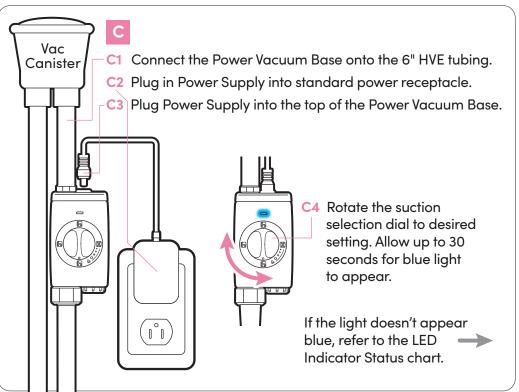
6868A Cortona Dr Santa Barbara, CA 93117 (805) 560-9888

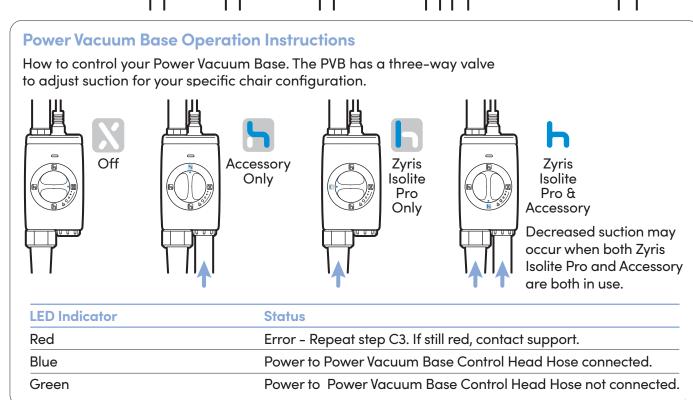


# INSTRUCTIONS FOR USE









### 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 visibilityEffective isolation
- Continuous suction for moisture control and aerosol/spatter reduction
- Airway protection
- Bite block for patient comfort and safety
- Reduced patient chair time

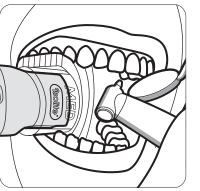
Depending on procedure needs, determine which Zyris Isolite® Mouthpiece will work best.

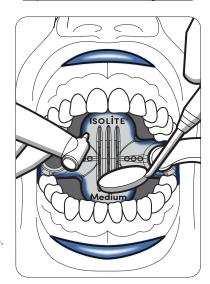
For posterior or quadrant-based procedures that need intraoral illumination, connect the Posterior Vacuum Light Pipe to Control Head with our posterior mouthpiece.

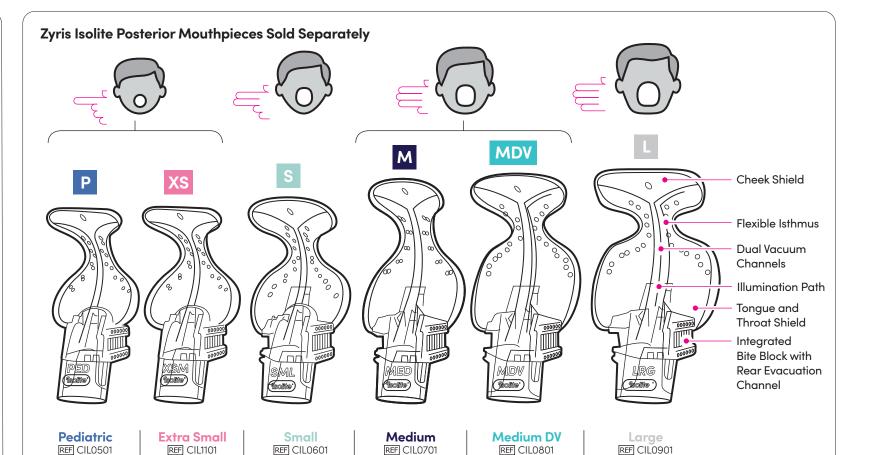
See "Posterior Procedures" in next steps.

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.





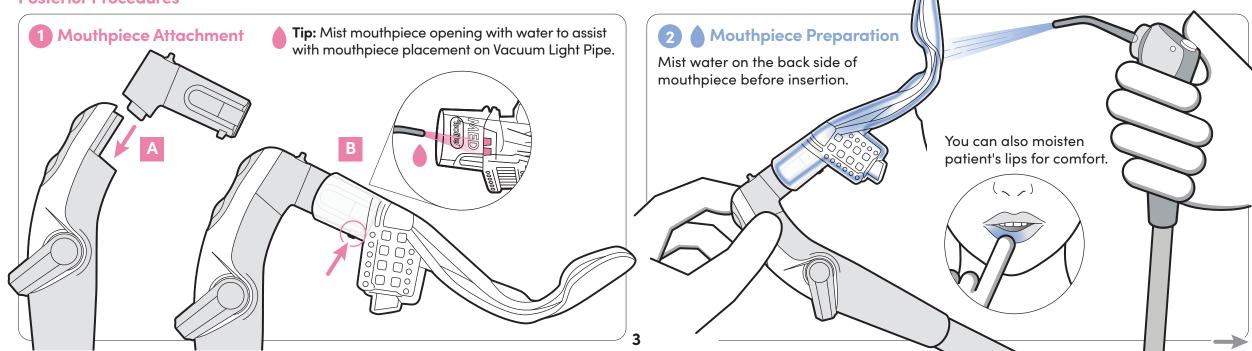


Bite Block 30 mm

Bite Block 30 mm

Bite Block 33 mm

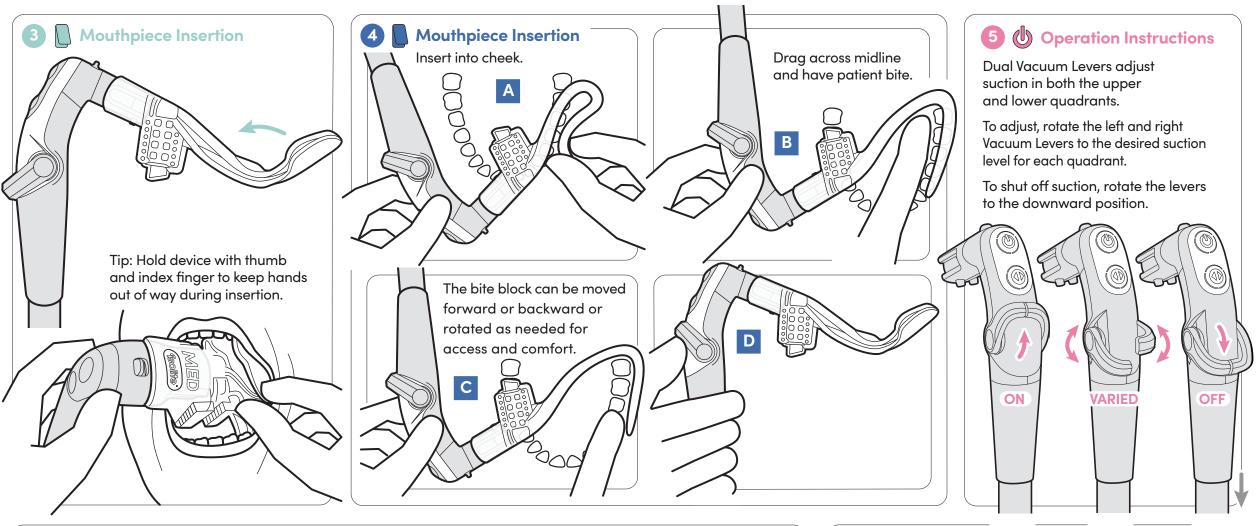


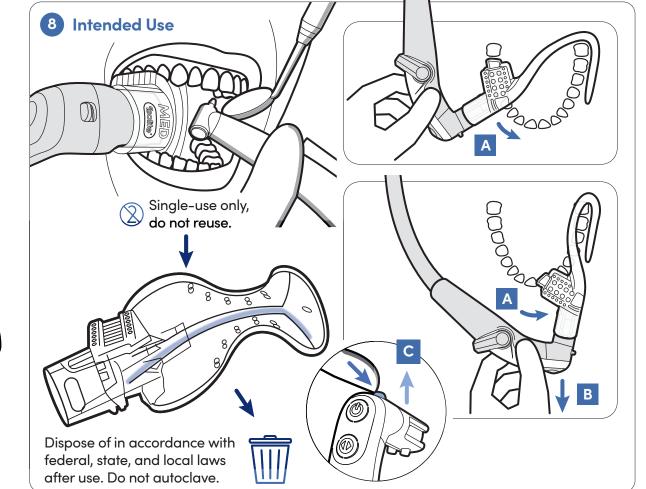


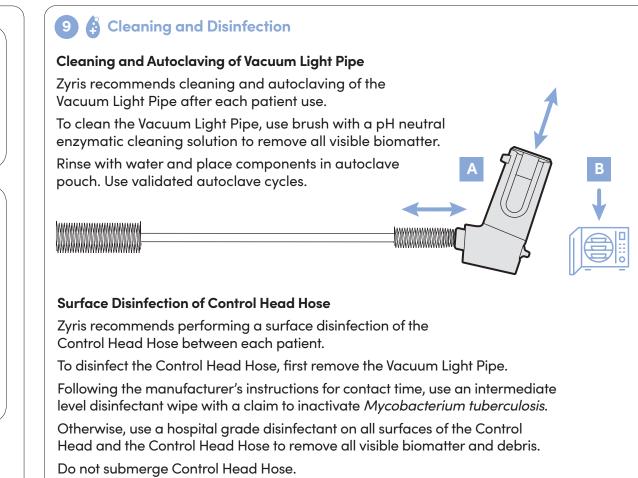
Bite Block 25 mm

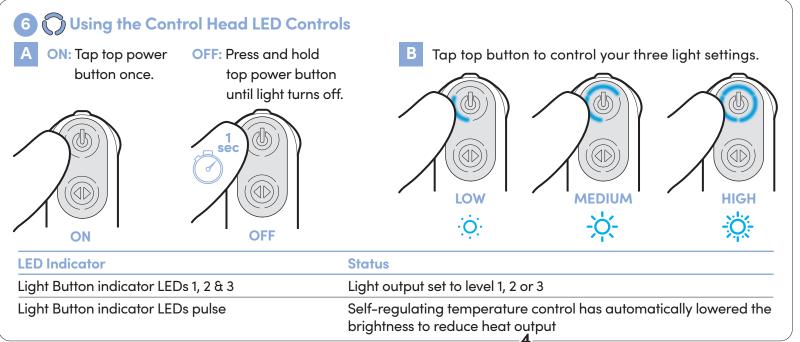
Bite Block 28 mm

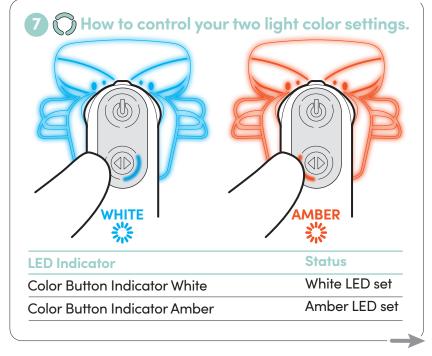
Bite Block 25 mm

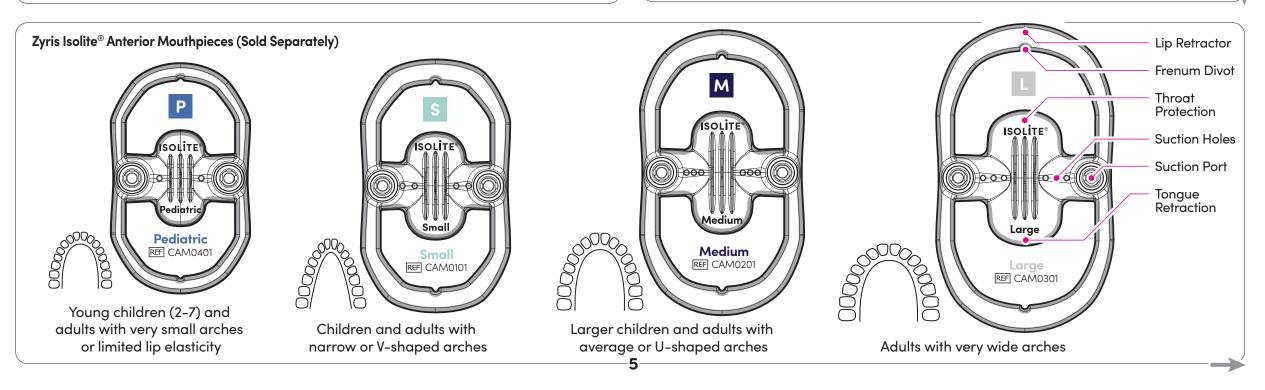


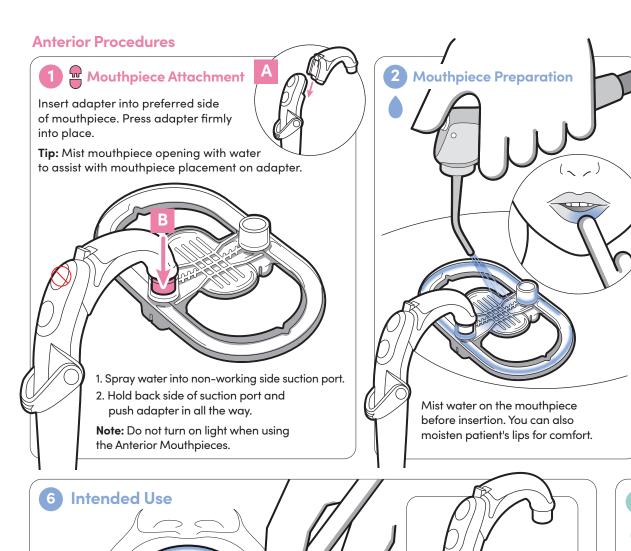


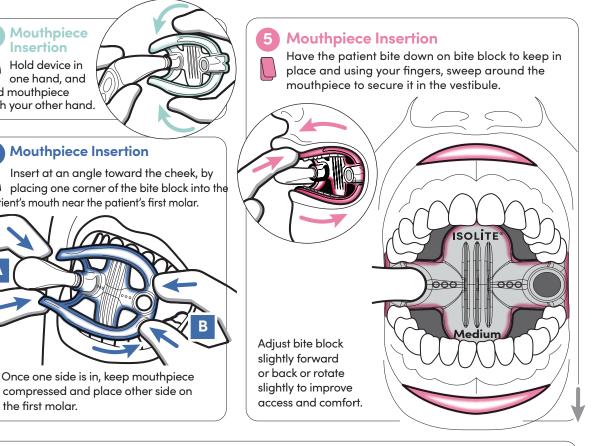


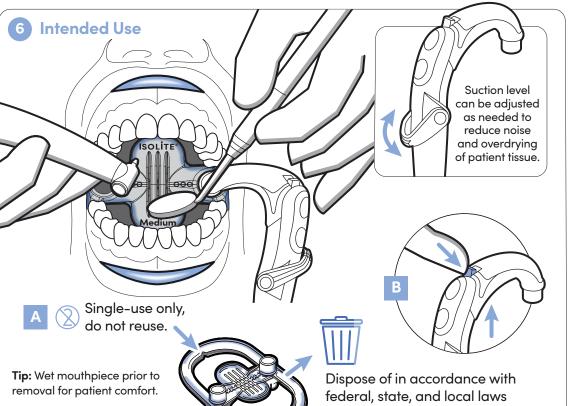




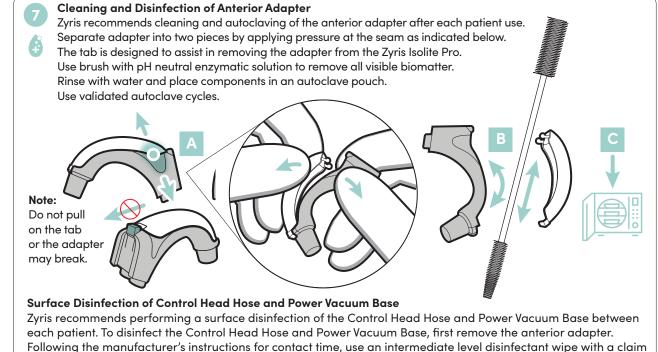








after use. Do not autoclave.



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.

Hold device in

with your other hand.

fold mouthpiece

one hand, and

Mouthpiece Insertion

patient's mouth near the patient's first molar.

C Once one side is in, keep mouthpiece

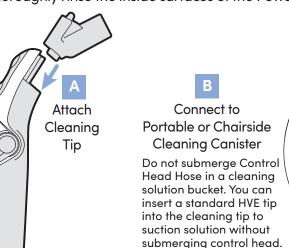
the first molar.

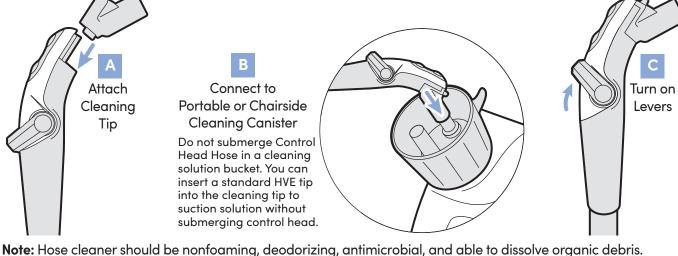
compressed and place other side on

## **Daily Maintenance**

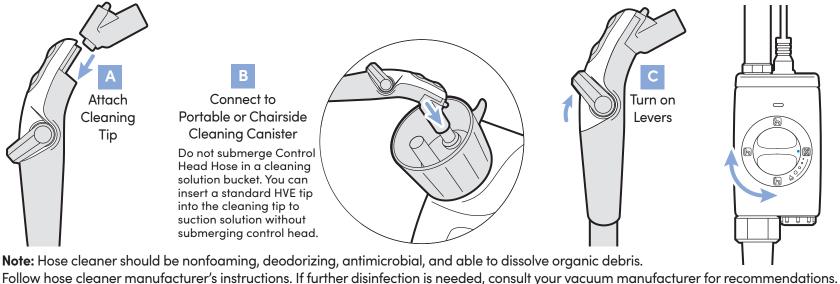
#### Control Head Hose and Power Vacuum Base Internal Surfaces

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.





At a minimum, open and close valves daily, to keep hose dry from other suction devices connected to the same suction canister.



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

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

Weekly Maintenance Zyris recommends cleaning and maintaining the Control Head Hose and Power Vacuum Base weekly. 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. Match • (Left) and •• (Right) inside of lever to match on Control Head Hose for placement.

