

## 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	132 °C / 270 °F	4 min	20 min
Prevacuum	134 °C / 273 °F	3 min	20 min

## CONTRAINDICATIONS

No known contraindications. Do not use without reviewing how to select the correct Isolite Mouthpiece size for each patient. Do not use if unable to position the Isolite 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.

## WARNINGS

**WARNING:** 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 Isolite Mouthpiece package has been previously damaged or opened. Non-sterile Isolite Mouthpieces are individually packaged in polyethylene bags.

**WARNING:** Be sure to use established protocols and patient monitoring when using the Isolite Mouthpiece 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 Isolite Pro device. 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](https://Zyris.com/i3-optout).

## PRECAUTIONS

**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 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 Power Hose to shut off suction. Internal damage to the Power 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.

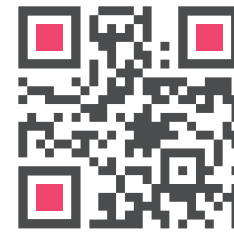
**CAUTION:** Do not autoclave any components at temperatures above 135 °C; higher temperatures could damage components and void your product warranty.

**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 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>



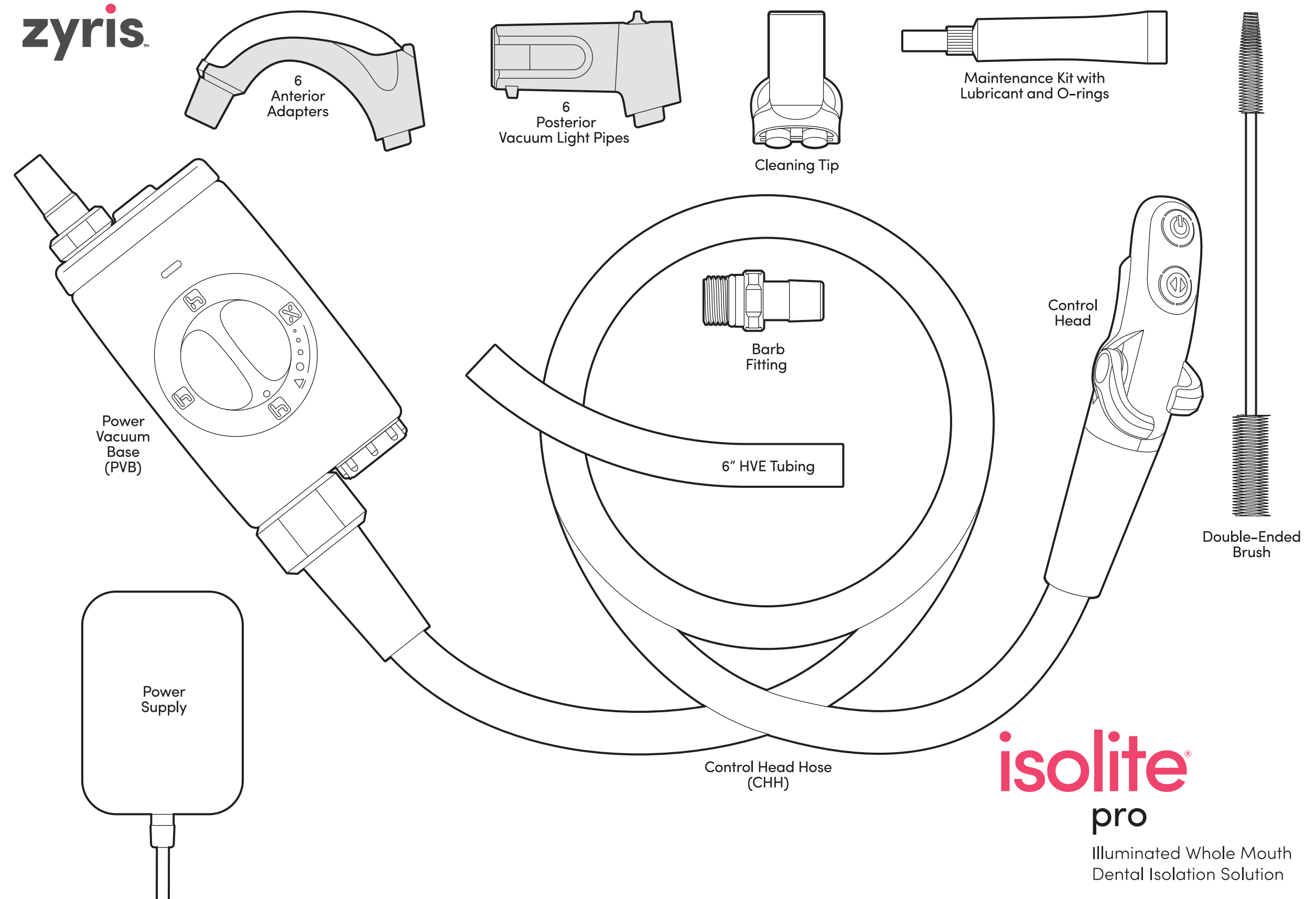
recyclable paperboard

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

**zyris**

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

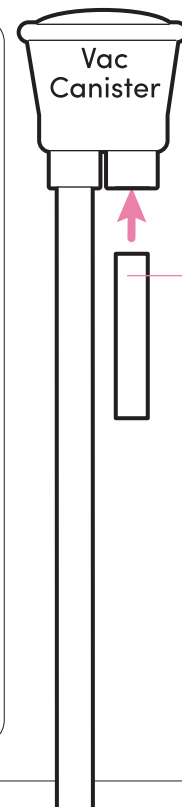
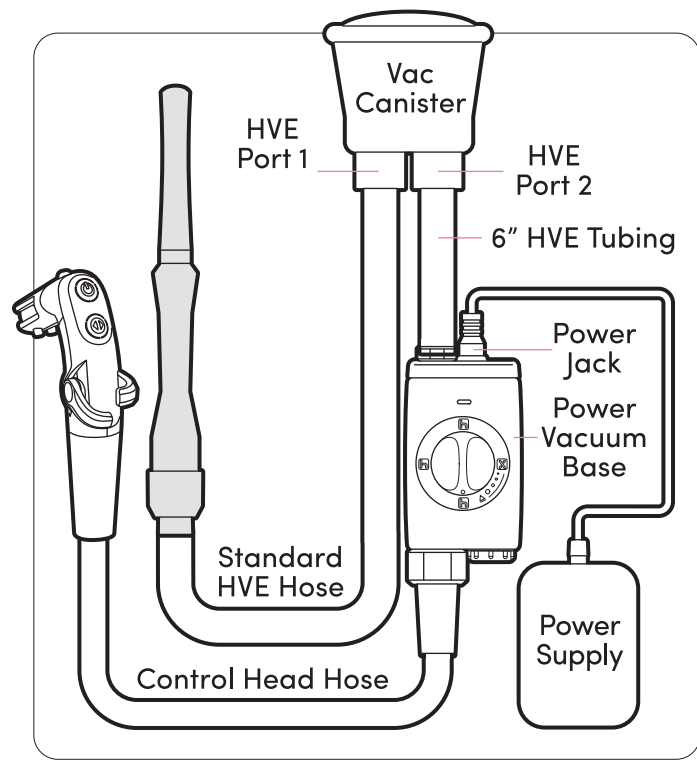
96-0812 Rev A



**isolite**  
pro

Illuminated Whole Mouth  
Dental Isolation Solution

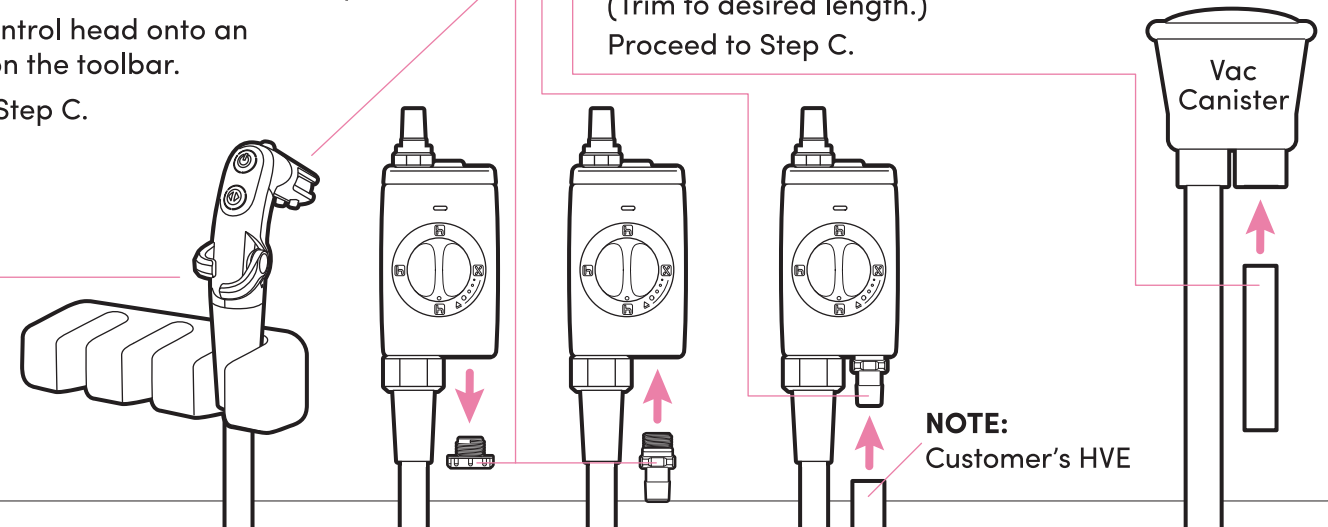
**Installation Instructions** Determine the HVE connection technique for Isolite Pro.  
**NOTE:** If you do not have an open slot on your toolbar, contact your distributor.



**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.

**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.

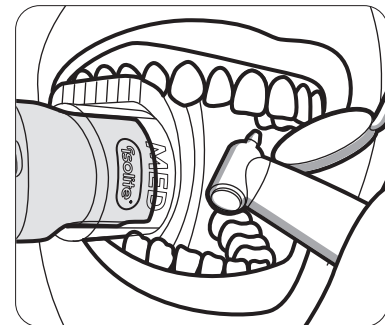


**NOTE:** Customer's HVE

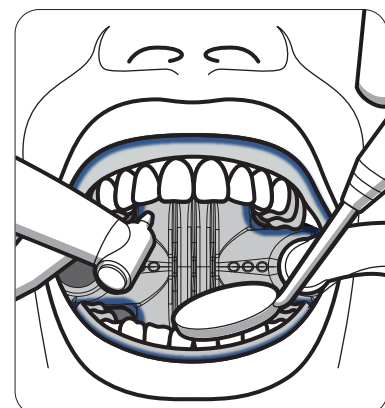
**Intended Use**

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

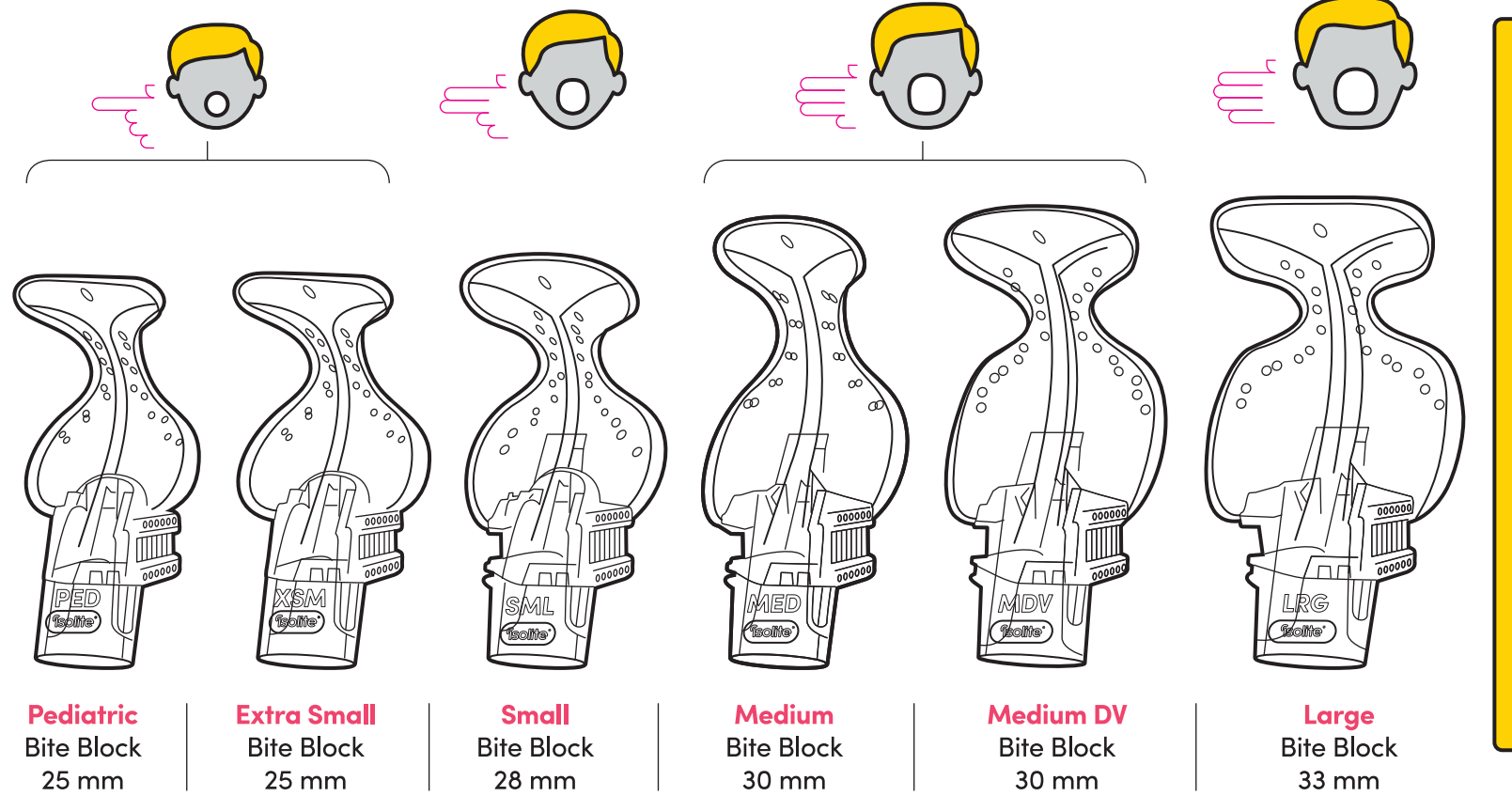
For Posterior or Quadrant based procedures that need intraoral illumination, connect the Posterior Vacuum Light Pipe to control head with an Isolite Posterior Mouthpiece.



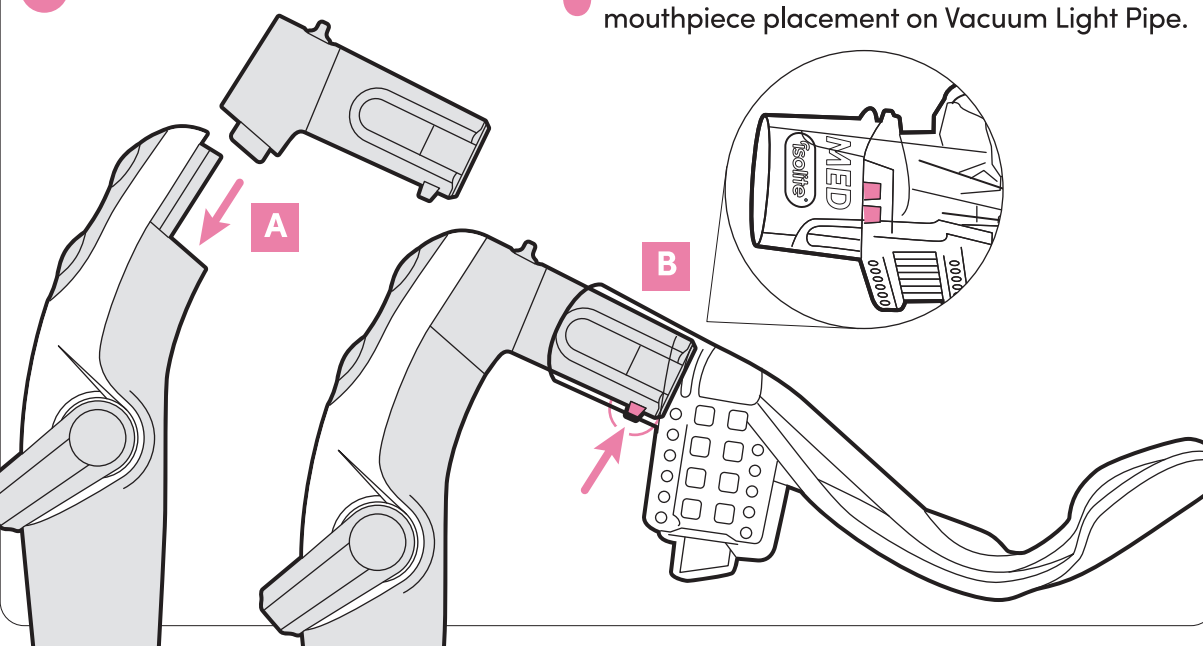
For Anterior or bicuspid to bicuspid procedures, connect the Anterior Adapter to the Control Head with an Isolite Anterior Mouthpiece.



**Isolite Posterior Mouthpieces Sold Separately**



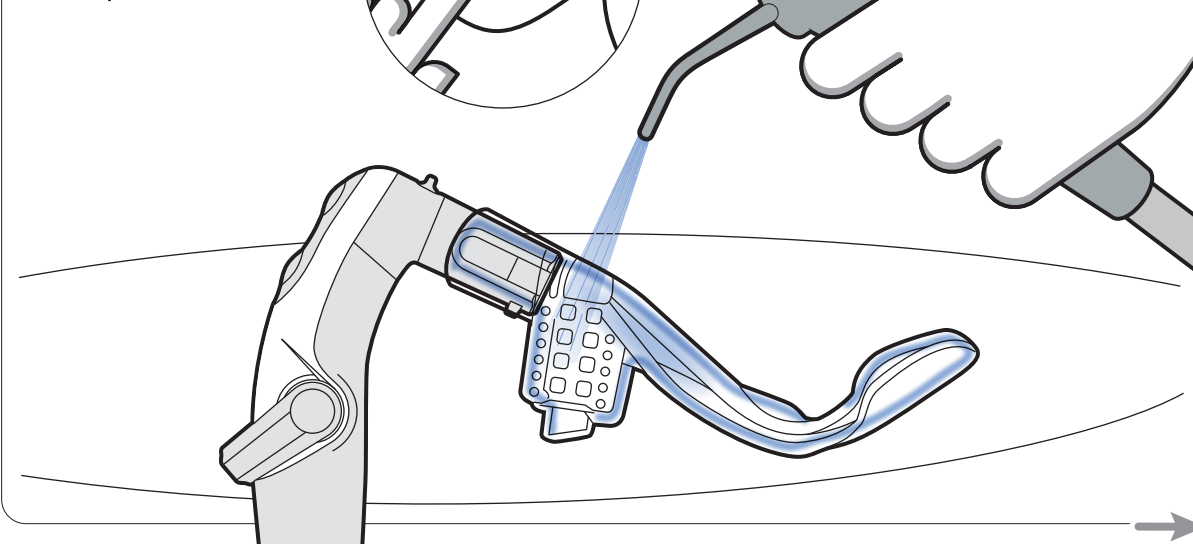
**1 Posterior Procedures**



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

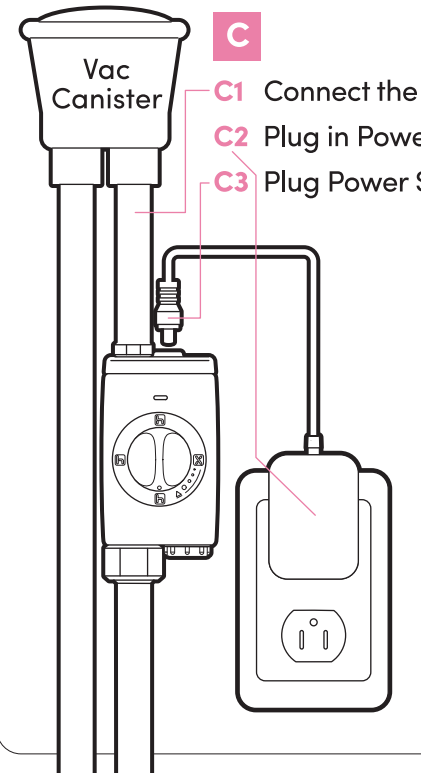
**2**

Lubricate mouthpiece and lips with water.



**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.

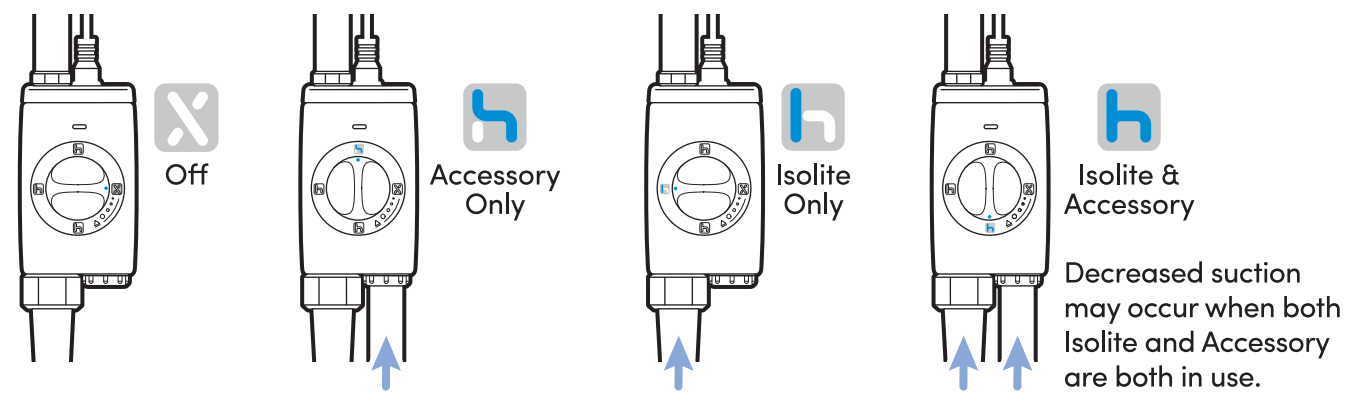


**C4** Rotate the suction selection dial to desired setting. Allow up to 30 seconds for blue light to appear.

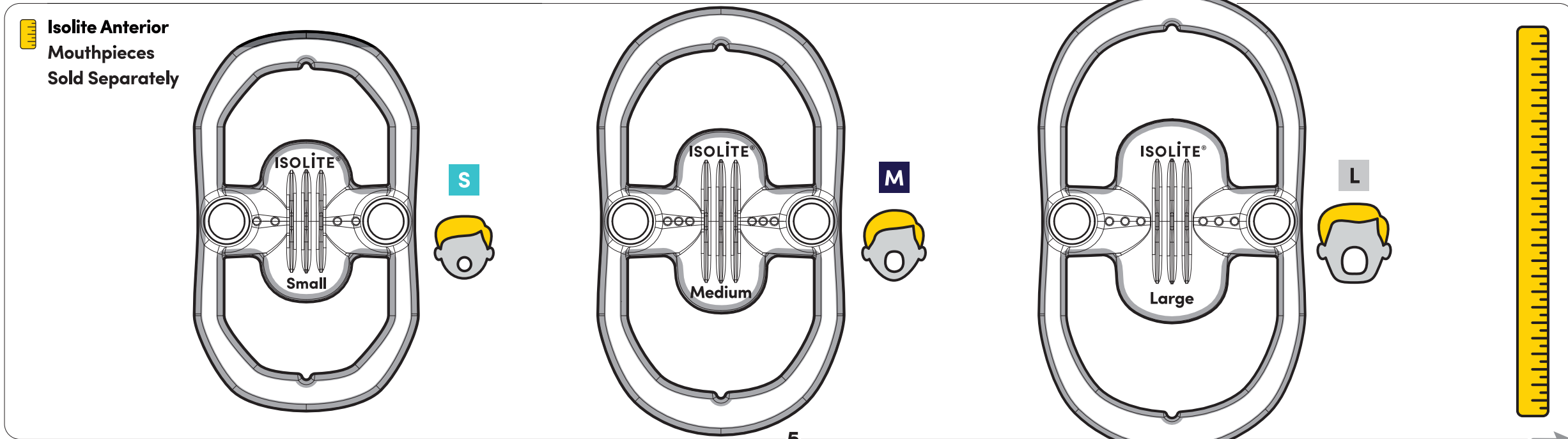
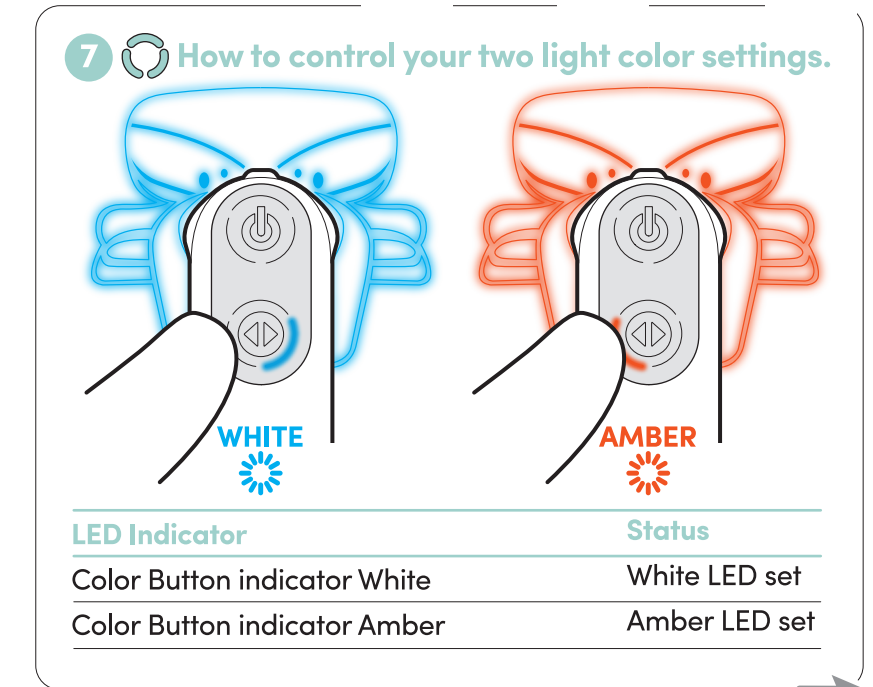
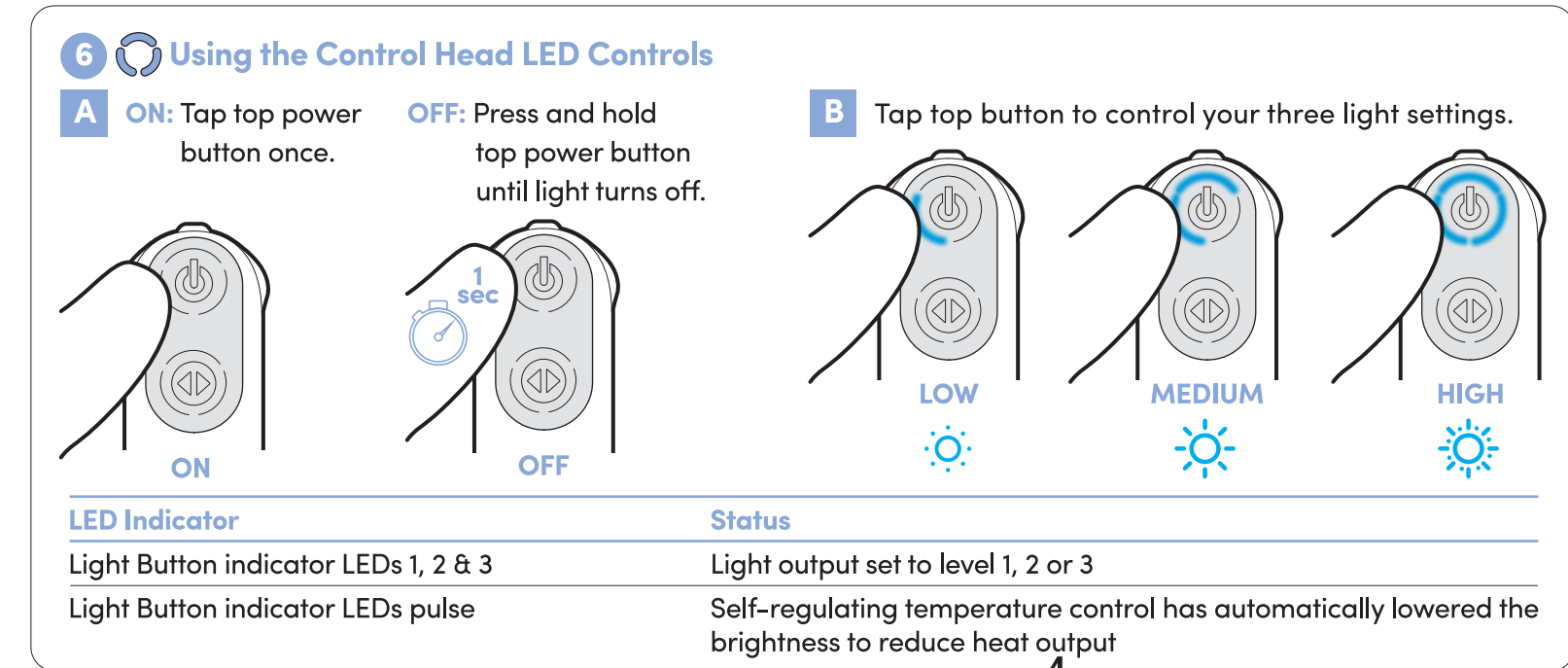
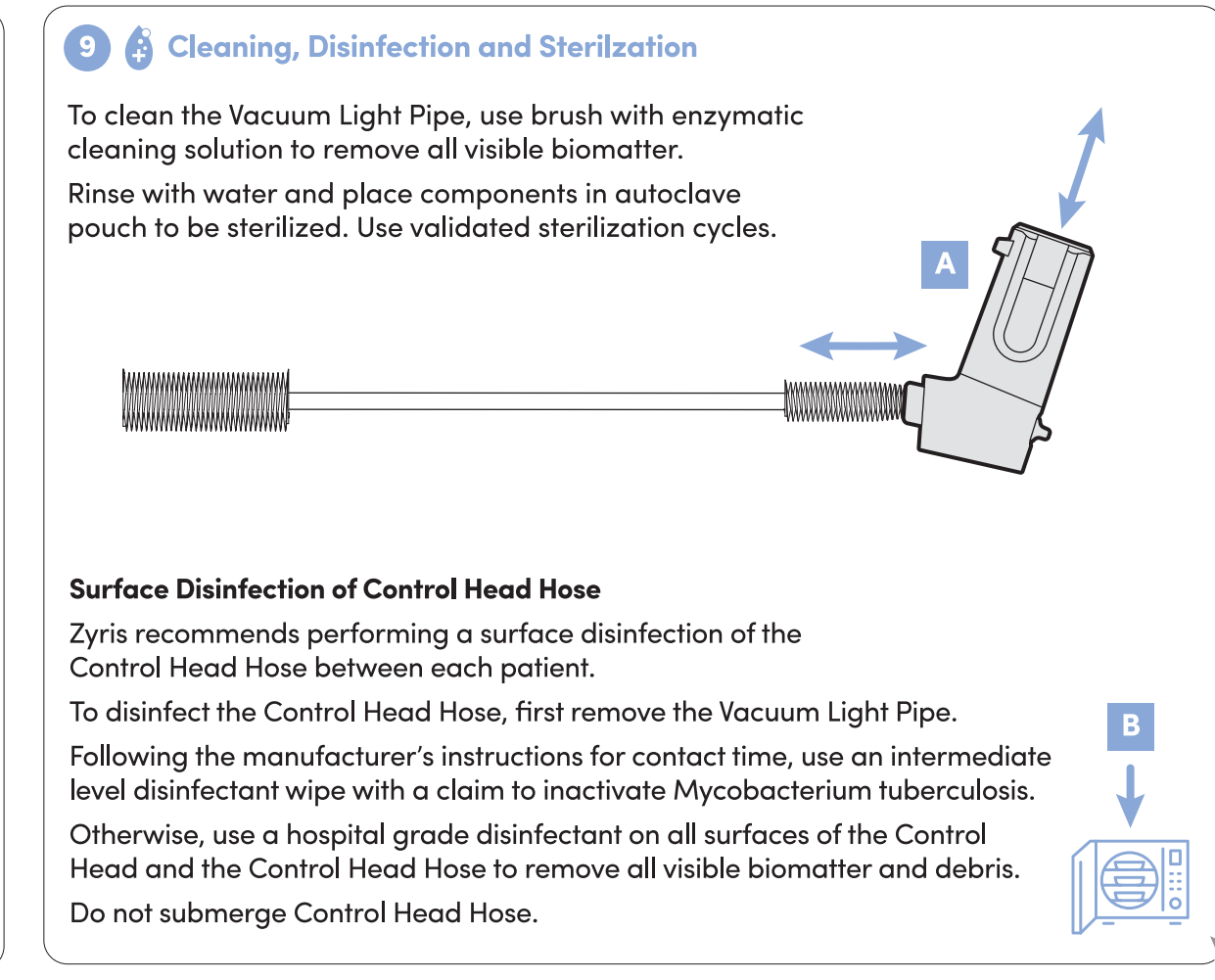
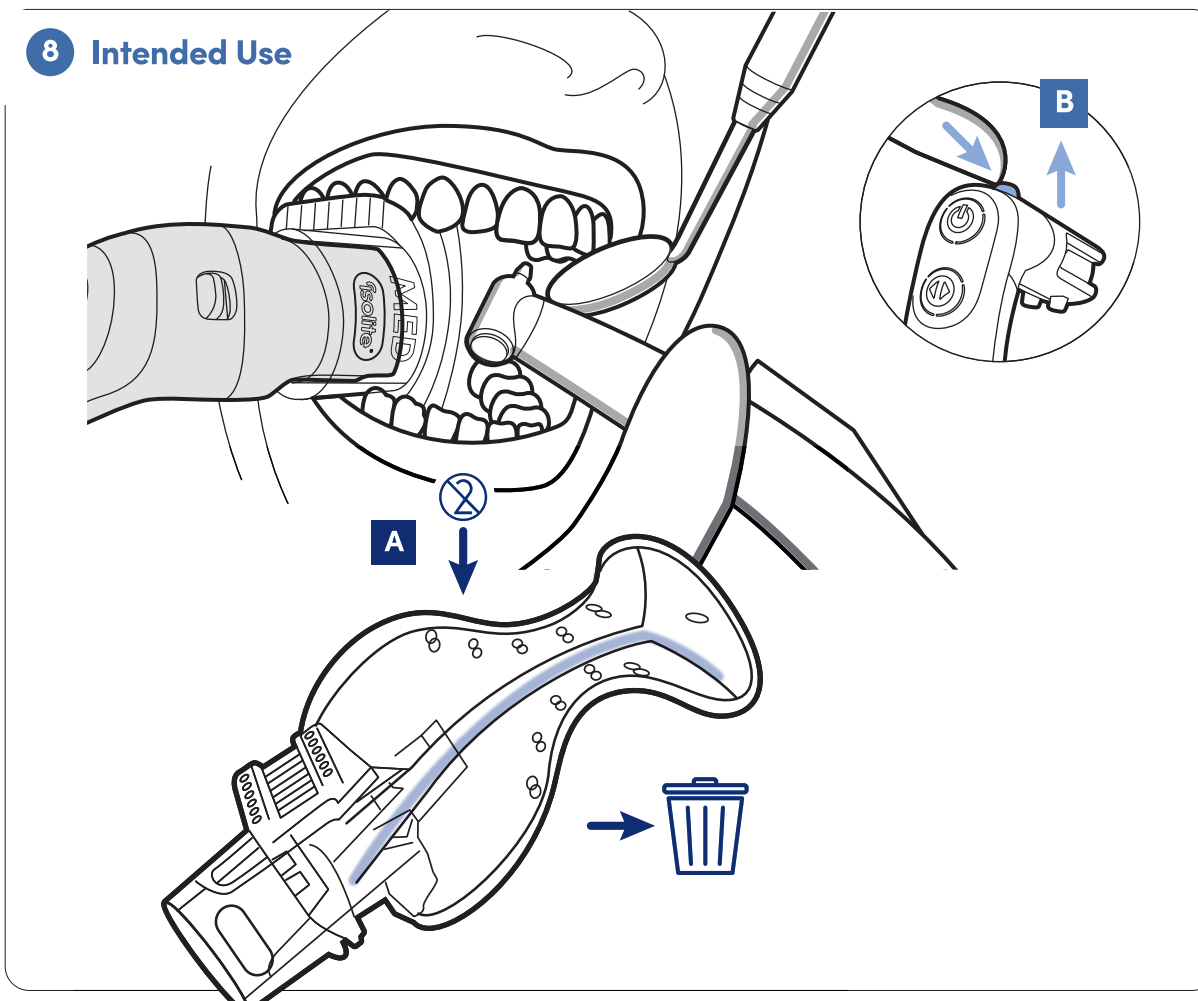
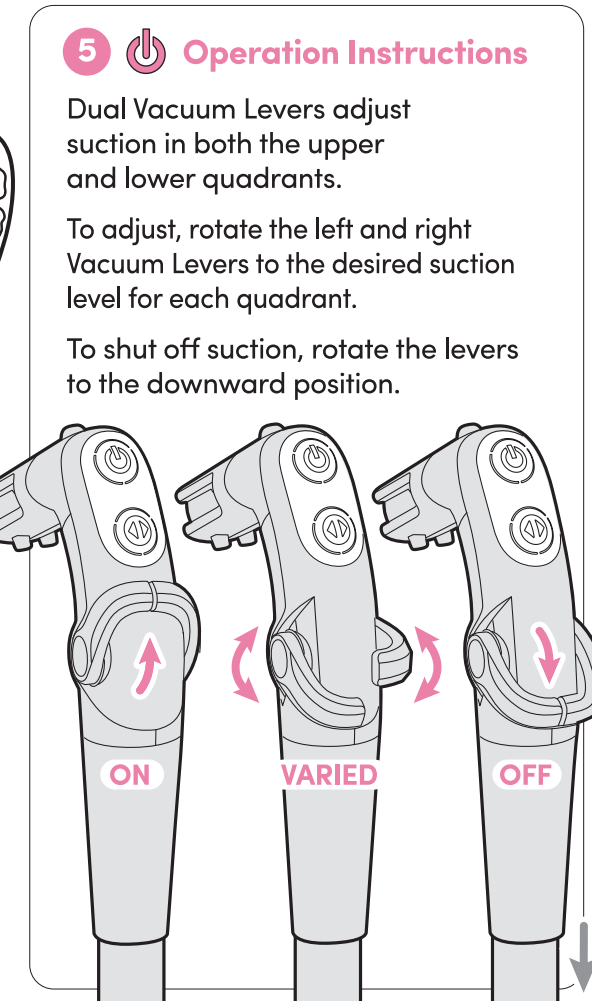
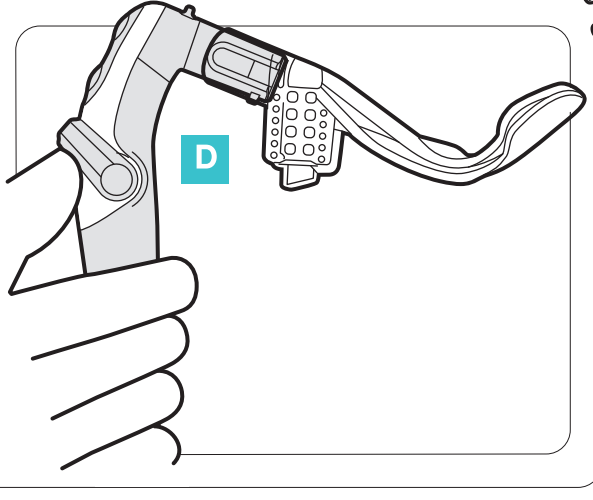
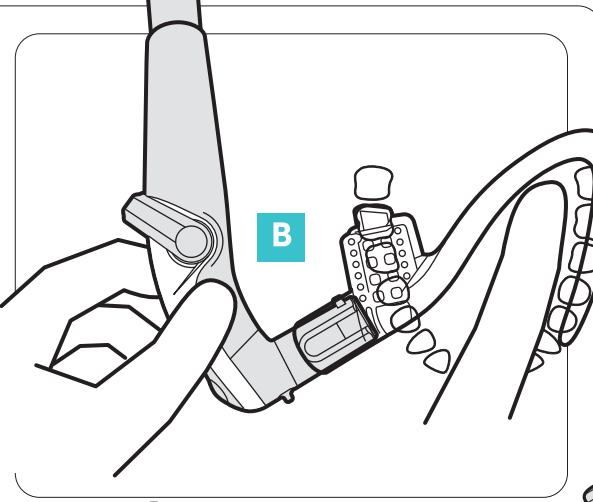
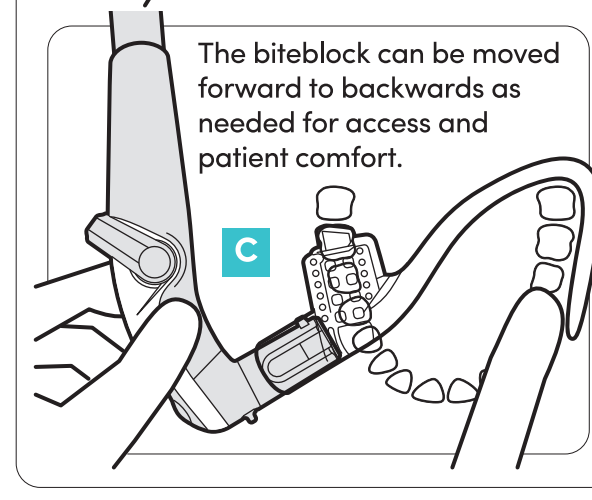
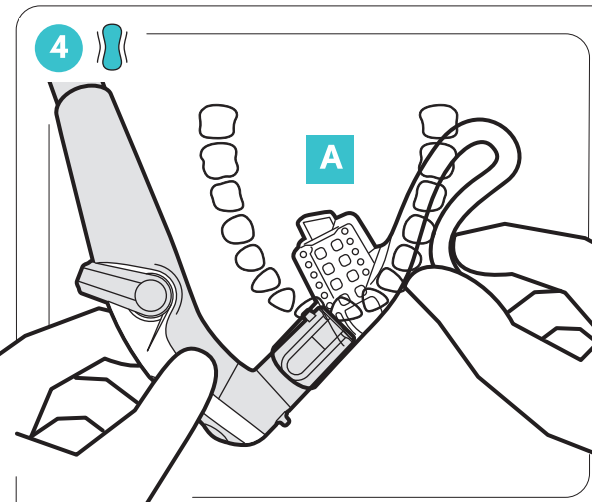
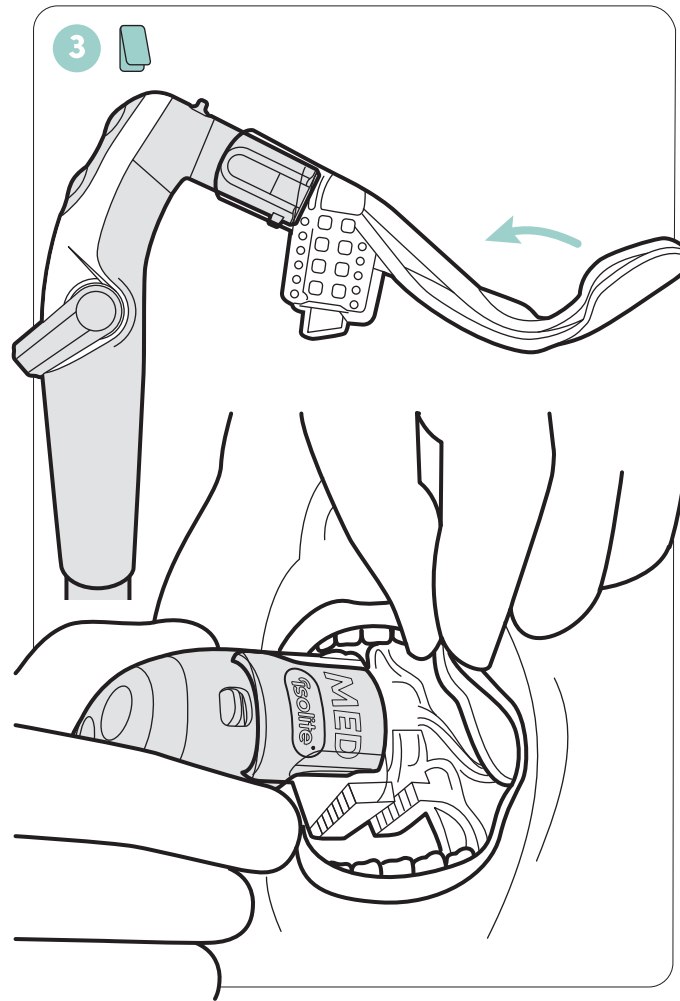
If the light doesn't appear blue, refer to the LED Indicator Status chart.

**Power Vacuum Base Operation Instructions**

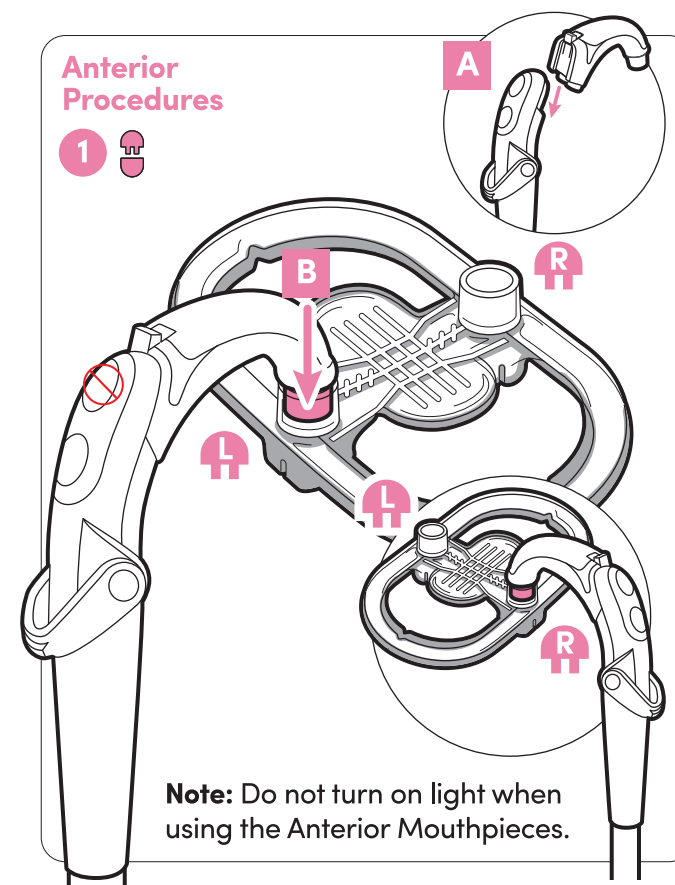
How to control your Power Vacuum Base. The PVB has a three-way valve to adjust suction for your specific chair configuration.



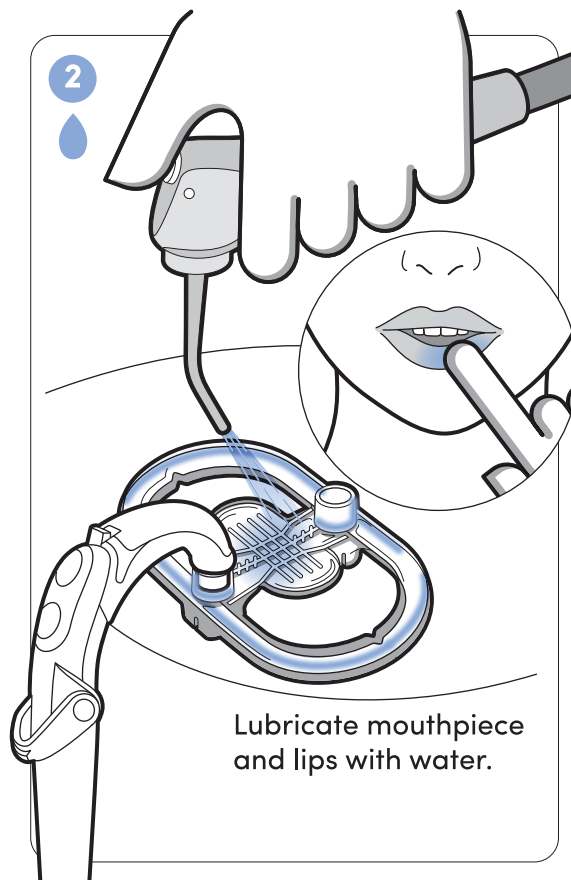
LED Indicator	Status
Red	Error - Repeat step C3. If still red, contact support.
Blue	Power to Power Vacuum Base Control Head Hose connected.
Green	Power to Power Vacuum Base Control Head Hose not connected.



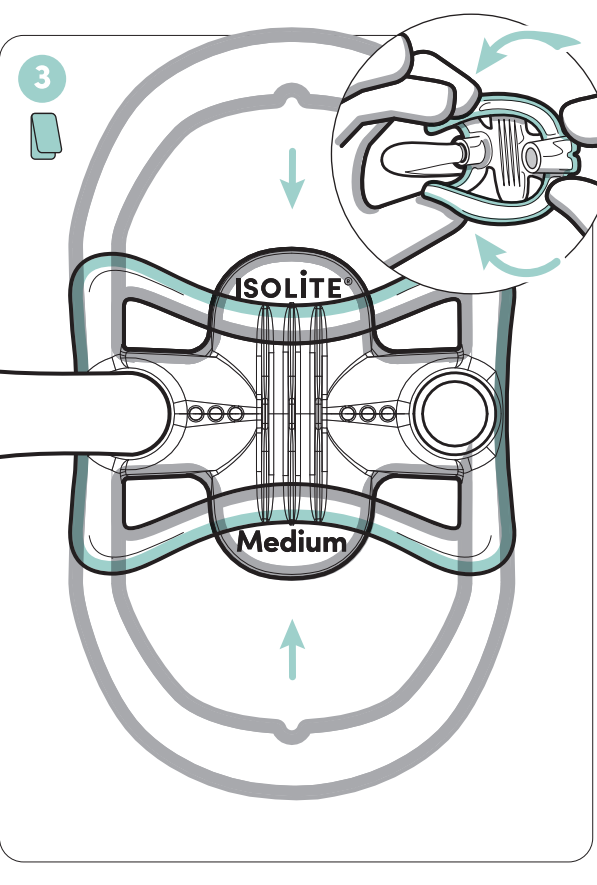
**Anterior Procedures**

**1** 

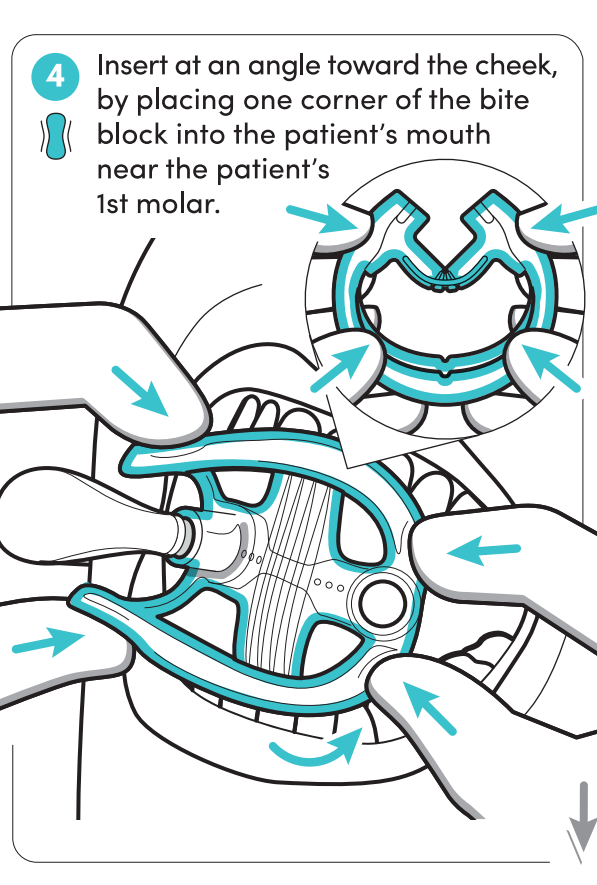
**Note:** Do not turn on light when using the Anterior Mouthpieces.

**2** 

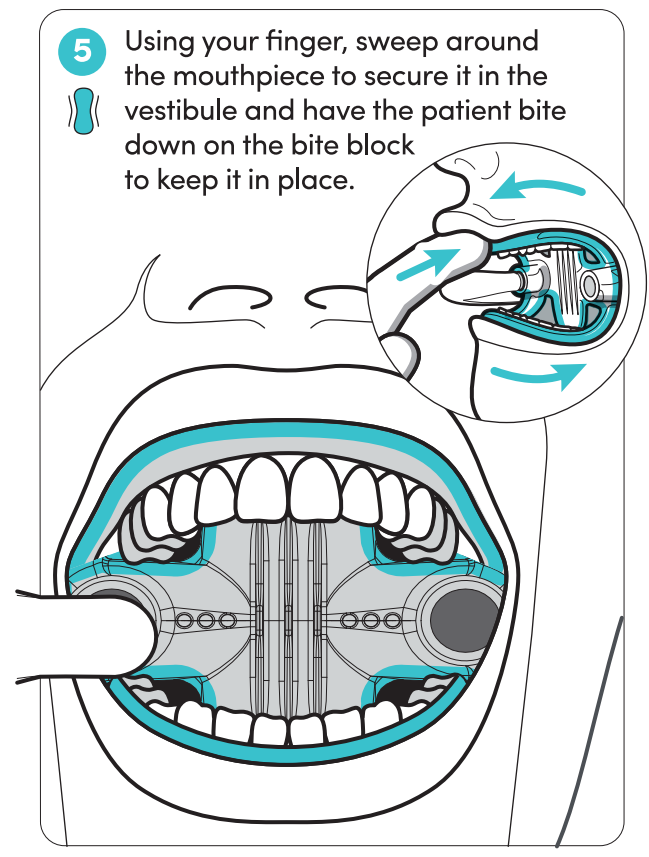
Lubricate mouthpiece and lips with water.

**3** 

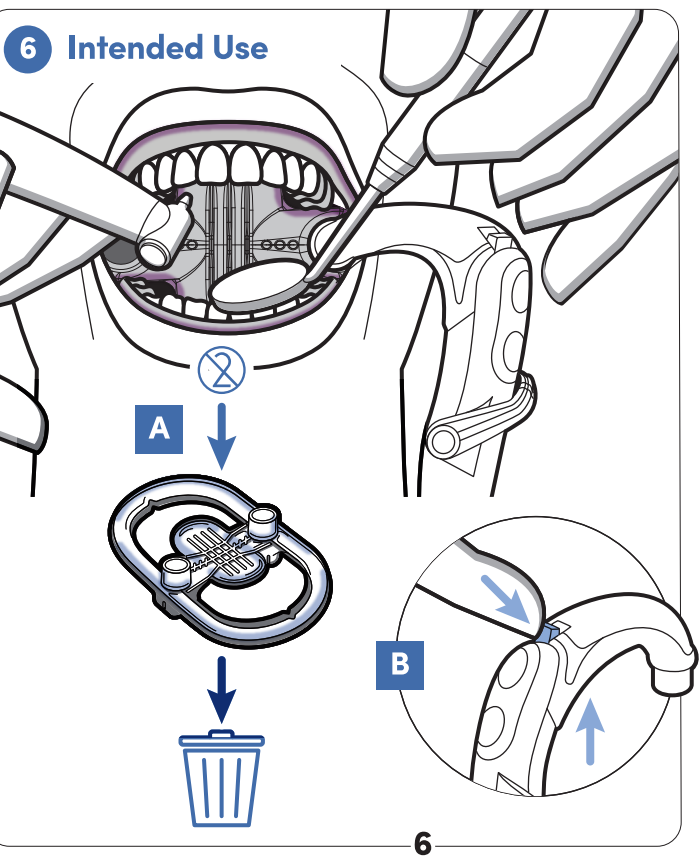
**4** Insert at an angle toward the cheek, by placing one corner of the bite block into the patient's mouth near the patient's 1st molar.



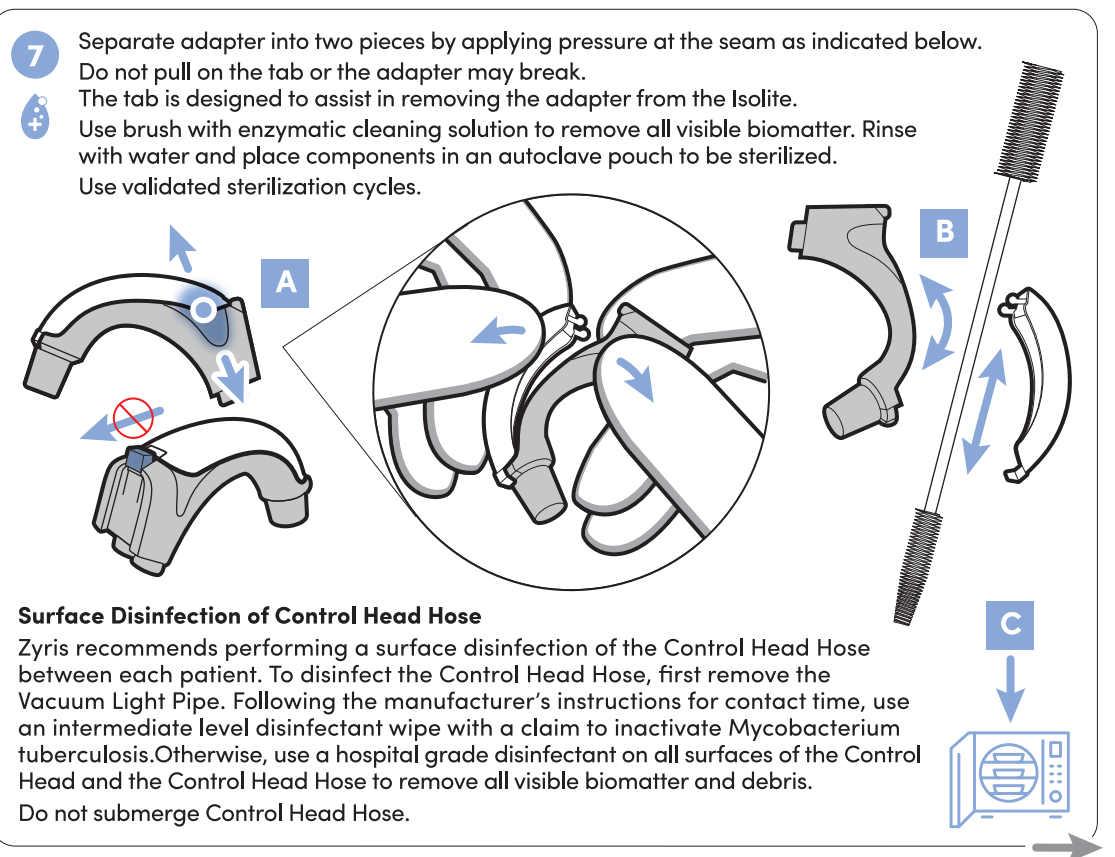
**5** Using your finger, sweep around the mouthpiece to secure it in the vestibule and have the patient bite down on the bite block to keep it in place.



**6 Intended Use**



**7** Separate adapter into two pieces by applying pressure at the seam as indicated below. Do not pull on the tab or the adapter may break. The tab is designed to assist in removing the adapter from the Isolite. 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.



**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.

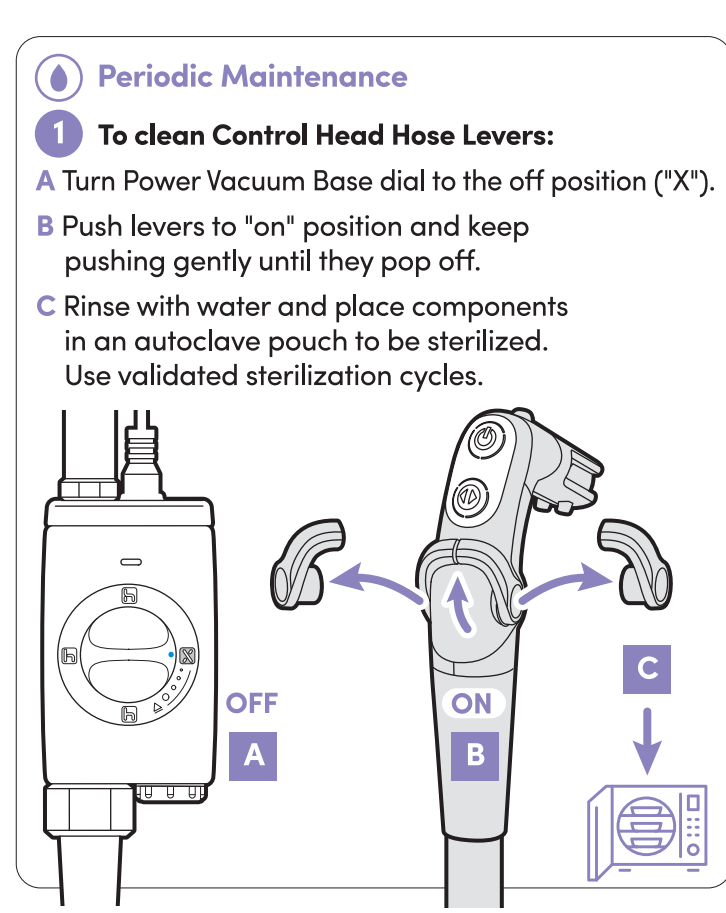
**Periodic Maintenance**

**1 To clean Control Head Hose Levers:**

**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.

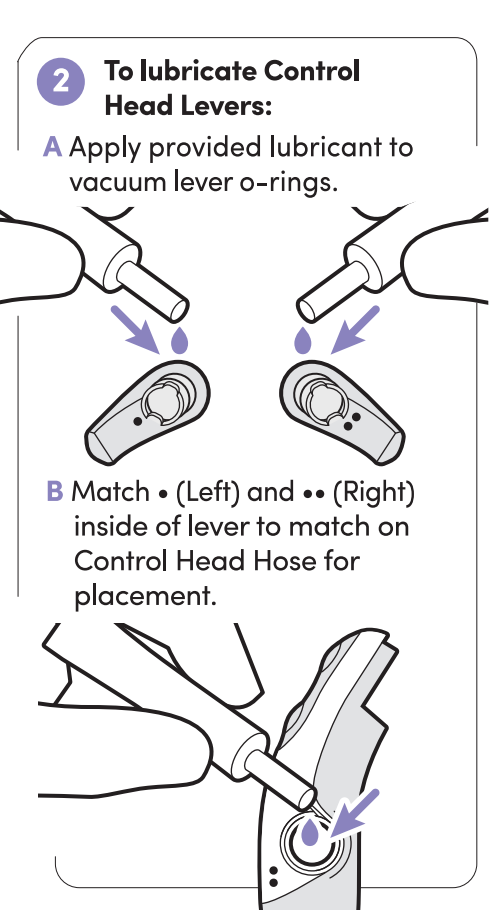
**C** Rinse with water and place components in an autoclave pouch to be sterilized. Use validated sterilization cycles.



**2 To lubricate Control Head Levers:**

**A** Apply provided lubricant to vacuum lever o-rings.

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



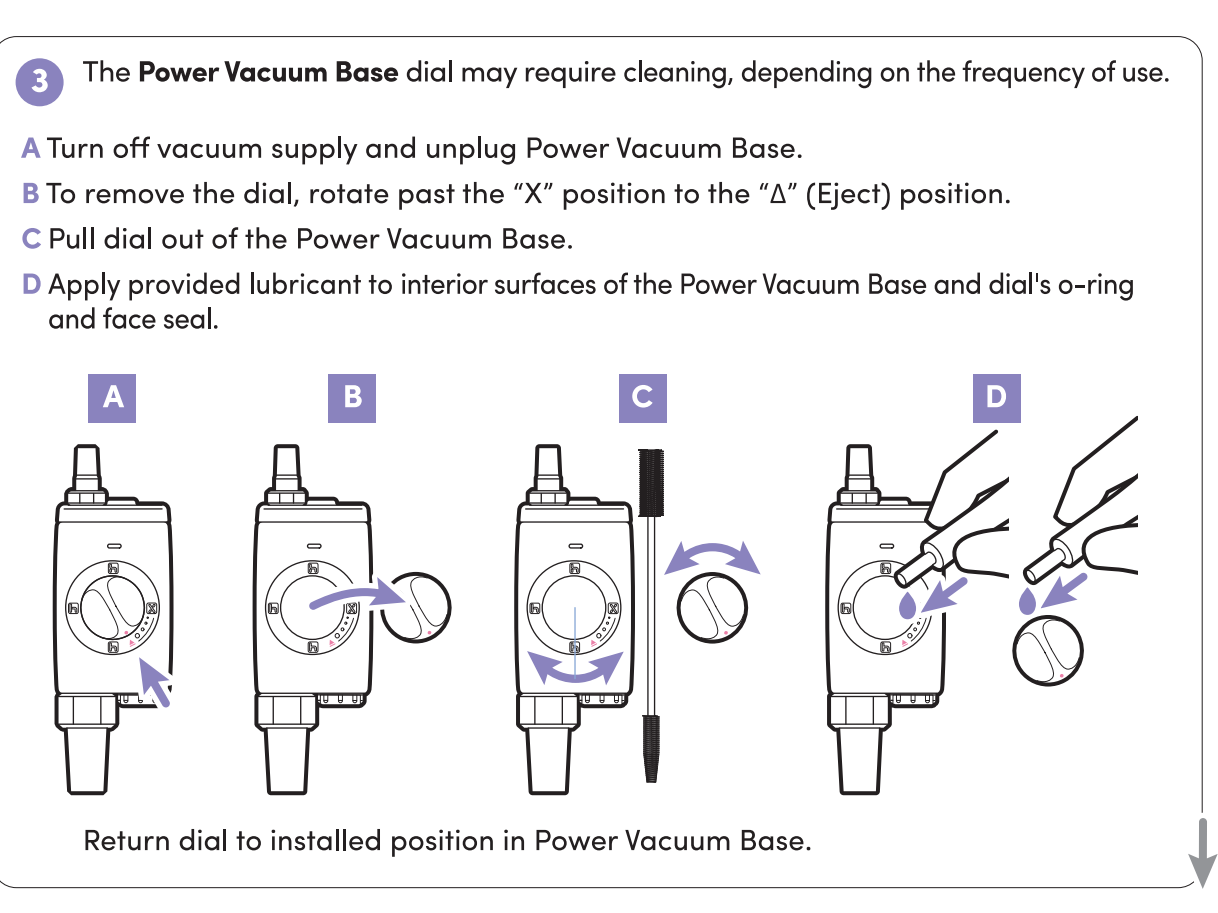
**3 The Power Vacuum Base dial may require cleaning, depending on the frequency of use.**

**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.

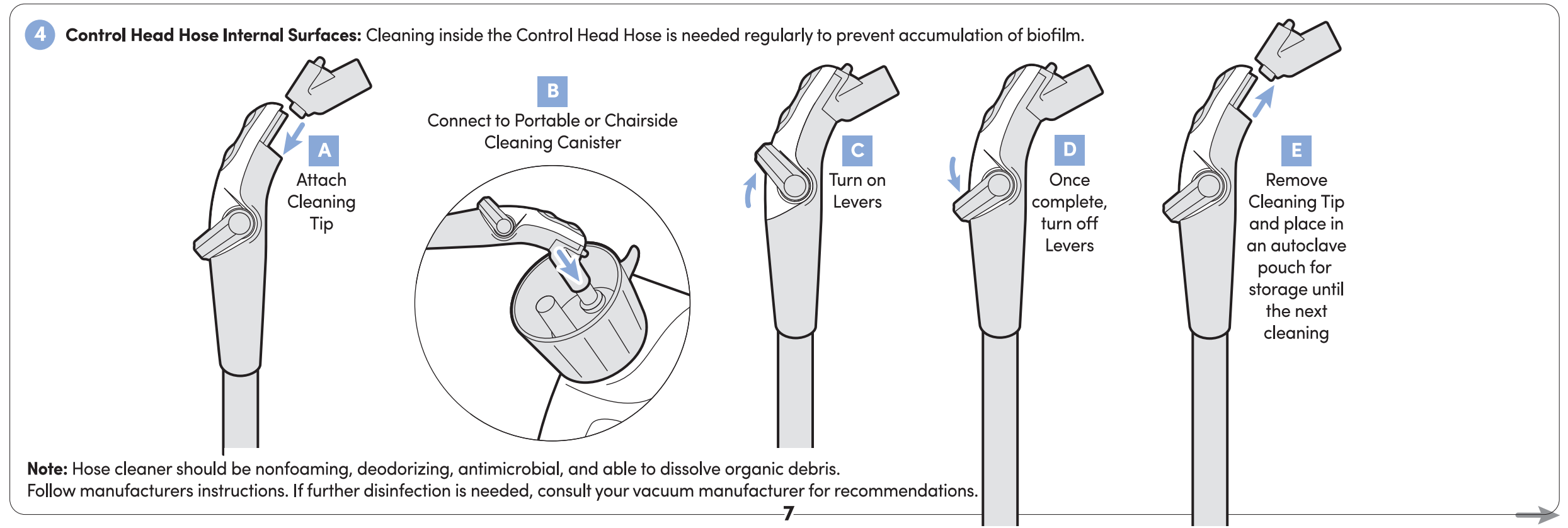
**C** Pull dial out of the Power Vacuum Base.

**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.

**4 Control Head Hose Internal Surfaces:** Cleaning inside the Control Head Hose is needed regularly to prevent accumulation of biofilm.



**A** Attach Cleaning Tip

**B** Connect to Portable or Chairside Cleaning Canister

**C** Turn on Levers

**D** Once complete, 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 manufacturers instructions. If further disinfection is needed, consult your vacuum manufacturer for recommendations.