

Read these instructions for use carefully before operating.
Keep it in a safe place for further consultation.



iVocTM

**Apical Negative Pressure Irrigation
and Activation System**

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1. Introduction

Thanks for purchasing the iVac™ **Apical Negative Pressure Irrigation and Activation System** introductory kit.

The **Pac-Dent** medical device you are about to install and use in your practice is designed for professional use. It contains the chosen tool with which you will provide treatment within the context of your work.

Please read the documentation provided carefully to ensure optimum safety for yourself and your patients, comfort in your daily practice, and the full benefits of your medical device's technology.

If you have received it by mistake, don't hesitate to contact the supplier to arrange for it to be collected.

The iVac system is intended for irrigation, ultrasonic activation, and evacuation of endodontic solutions during root canal treatment.



IMPORTANT:

- a. **The piezo ultrasonic device recurrently mentioned in these instructions for use is not included with the introductory kit.**
- b. The manufacturer highly recommends using the **iVac™** LED Piezo Ultrasonic Scaler unit (Pac-Dent) with the iVac system.



WARNINGS:

- a. Read all instructions before operating this medical device. The manufacturer accepts no liability for any damage resulting from improper use of this device and/or for any purpose other than those covered by these instructions.
- b. Use only for the intended use. Failure to comply with the operating instructions may result in serious injury to the patient or operator. Therefore, verify that you have read and understood the operating instructions before operating this device.
- c. U.S. Federal law restricts this device to sale by or on the order of a dentist.
- d. As per Endodontic Standards of Care, **always use a rubber dam isolation when performing endodontic treatment.**
- e. The connector on the introductory kit is used with an **S-type (M3,0 x 0,6 AG) piezo ultrasonic handpiece**. Therefore, do not install it on an E-type (M3,0 x 0.5 AG) piezo ultrasonic handpiece. Instead, consult your piezo ultrasonic device instructions for use about the device's compatibility (S or E-type tips). **An E-type iVac ultrasonic connector (REF#9542EC) is sold separately.**
- f. Do not use dry heat sterilization on any of the device's components.
- g. Do not perform repairs or change to the device without prior consent from **Pac-Dent**. In the event of an abnormality, contact **Pac-Dent**.

1.1 Operator population: Operation of this medical device is limited only to certified, capable, and qualified dental professionals in their regular place of business. The operator must master and comply with the rules of dental practice per science and principles of medical hygiene, such as the cleaning, disinfection, and sterilization of medical devices. This medical device may be used regardless of the characteristics of the (adult) operator, such as weight, age, height, sex, and nationality. However, staff and the operator should wear gloves and eye protection.

1.2 Patient population: this medical device is intended for use with the following patient population: children, teenagers, adults, and senior citizens.

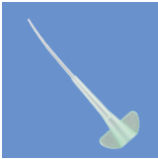

1.3 Body parts or tissue types treated: treatment should be limited only to the patient's buccal cavity.



2. Product configuration



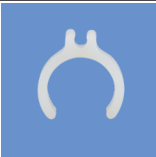
The iVac™ introduction kit (REF#9542IVC) Contents:

- 5 x 0.35 iVac tips 27mm
- 5 x 0.50 iVac tips 27mm
- 1 x iVac S-type piezo connector
- 10 x Angled capillary tips
- 1 x Low Vac adaptor
- 1 x High Vac adaptor
- 5 x Short silicone tubing with 1 female connector and 1 elbow connector
- 1 x Long silicone tubing with 1 female connector and 1 male connector
- 2 x Rings
- 1 x Technique Guide
- 1 x Instructions for Use

The iVac™ system Refill kit components:

REF#	Description	Figure	Usage cycle
954235G	20x iVac 0.35 tips 27mm (Green)		Sterilize before use. Discard it after use.
954250Y	20x iVac 0.50 tips 27mm (Yellow)		Sterilize before use. Discard it after use.

REF#	Description	Figure	Usage cycle
9542SC	1x iVac S-type piezo connector , 2 x Rings		Sterilize before use. Reusable.
9542EC	1x iVac E-type piezo connector, 2 x Rings		Sterilize before use. Reusable.

REF#	Description	Figure	Usage cycle
9542ACT	10x Angled capillary tips 0.60mm		Sterilize before use. Discard it after use.
9542ST	5x Short (170mm) silicone tubing with 1 female connector and one elbow connector		Sterilize before use. Discard it after 5 sterilization cycles.
9542R	2x Rings		Sterilize before use. Discard it after 5 sterilization cycles.




i IMPORTANT:

- The iVac system should preferably be used with a piezo ultrasonic device. The introductory kit **does not include piezo ultrasonic device** (also known as a **piezo ultrasonic scaler**). The piezo ultrasonic handpiece connected with the iVac ultrasonic connector (included in this introductory kit) must be an **S-type (80756 M3,0 x 0,6 AG)**.

- The manufacturer recommends using the **iVac™ LED Piezo Ultrasonic Scaler (Pac-Dent)** with the iVac system.


3. Indications for use

The iVac system is intended for irrigation and evacuation during root canal treatment.

REF#	Description	Figure	Usage cycle
9542LTA	1x Long (1700mm) silicone tubing with 1 female connector and 1 male connector		Sterilize before use. Discard it after 5 sterilization cycles.
	1x Low Vac-adaptor		Sterilize before use. Discard it after 5 sterilization cycles.
	1x High Vac-adaptor		Sterilize before use. Discard it after 5 sterilization cycles.

4. Contraindications

When iVac is used with a piezo ultrasonic unit:

 Piezo ultrasonic units shall not be used in cases where a patient has been fitted with an implanted heart pacemaker (or other electrical equipment) and has been cautioned against using small electrical appliances (such as electric shavers, hair dryers, etc.).



CAUTION:

- The device must only be used in suitable locations and by specialized physicians licensed to practice dentistry.

5. Description of the device

The iVac System is designed to be used during the root canal treatment irrigation phase, preferably connected to a piezo ultrasonic handpiece. The system was created using the three most important concepts established by endodontic research and science for root canal irrigation and disinfection. The first concept adopted is **ultrasonic vibration**, which acts as a chemical catalyst of the irrigating solutions in conjunction with the transient cavitation and microstreaming effects, determining a chemical-mechanical cleaning action in areas of difficult access in the root canal. The second concept is **negative pressure**, by which the irrigation fluid moves from the pulp chamber to the apical limit without extruding beyond the foramen. And finally, **concomitant irrigation**, a principle whereby the volume of irrigating liquid is renewed continuously. Constant fluid replacement provokes ideal chemical activity by repositioning the solution for a new one. The iVac system united the three irrigation fundamentals in a single device, acting safely against the risk of liquid extrusion into the periapical tissue and activating the renewed fluid inside the canal. The system is composed of an aspiration/activation cannula with two options of outside diameters, .35mm and .50mm. The iVac connector is designed to easily hold the cannula and deliver the irrigating liquid properly while transmitting the vibration from the piezo ultrasonic handpiece. In addition, tubes and connections allow the ordinary vacuum to be coupled, adding negative pressure to the system.



WARNINGS:

- a. **Place rubber dam isolation before beginning endodontic treatment.** The operator must ensure the integrity of the seal.
- b. Protect the patient's eyes (with safety glasses) and clothing from sodium hypochlorite (or other irrigant fluids) splatter or spills.
- c. Operators and assistants should wear personal protective equipment (gloves, glasses, mask, among others).
- d. The user is responsible for the sterility of the parts of the iVac system for use.
- e. The iVac tip .35 (green) requires a **minimum** canal preparation size of at least a file size (ISO) 35 .04 taper to be placed to full working length. Likewise, for the iVac tip .50 to be set to full working length, it requires a **minimum** canal preparation size of at least a file size (ISO) 50 .04 taper.
- f. The iVac ultrasonic connector part of the introductory kit is an S-type (80756 M3,0 x 0,6 AG). Only use the iVac S-type connector on piezo ultrasonic devices that use S-type connectors. Placing the S-type connector on an ultrasonic handpiece of a different thread configuration **will cause partial or total damage** to the connector and handpiece. Consult the piezo ultrasonic device instruction manual or contact the company's customer service where the equipment was purchased for more information.
- g. It is recommended to use sodium hypochlorite up to 2% concentration. Higher concentrations of sodium hypochlorite can be harmful.
- h. For concomitant irrigation with the iVac to be possible, the pulp chamber must act as a tank to receive the irrigating fluid from the exit port located at the connector or from a syringe and cannula. **If the crown is compromised, create a temporary crown** using a composite restorative material.

6. Pre-operation processing

Before each use, the iVac system must be installed on the piezo ultrasonic handpiece and the ordinary vacuum system terminal. The specific steps are as follows:



WARNINGS:

- The parts included in the introductory kit are **not sterile**. Therefore, sterilize all components before use. Consult **11. Cleaning and sterilization** section.



CAUTION:

- The iVac ultrasonic connector part of the introductory kit is an S-type (80756 M3,0 x 0,6 AG). Therefore, only use the iVac S-type connector on piezo ultrasonic devices that use S-type connectors. The iVac E-type connector (REF#9542EC) is sold separately.

6.1. Open the iVac introductory kit box. Identify its components (consult **2. Product configuration**).



IMPORTANT:

- **The piezo ultrasonic device recurrently mentioned in these instructions for use is not included with the introductory kit.**

6.2. Install the rings on the piezo ultrasonic handpiece. Remove any insert or tip that may have been previously installed on the hand piece. Install one of the rings to the outer face of the handpiece. Position the second ring as shown in (Figure 1), leaving a space between them.



Figure 1.

6.3. Pick up one short tube and install it by connecting to the ring slot. Leave the elbow connector at the handpiece's tip end (Figure 2).



Figure 2.

6.4. Take the iVac ultrasonic S-type connector and install it on the handpiece. Start screwing it with your fingers in a clockwise motion. With a flat wrench, finish screwing with light pressure (Figure 3).



Figure 3.

6.5. Choose the iVac tip based on the final diameter preparation. There are .35 (green) and .50 (yellow) options. The iVac tip is a self-screwing type of device. Insert the tip into the connector threads space, and with light pressure, screw the tip all the way (Figure 4). After installing the tip, insert the elbow connector tightly to the iVac tip (Figure 5).

Figure 4.

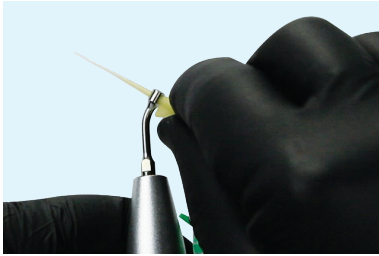
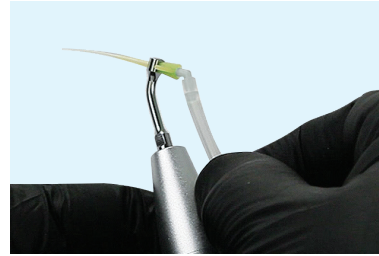


Figure 5.



i IMPORTANT:

a. For a better vibration transmission, ensure to screw the iVac tip to the end of the threads, ensuring that the base of the tip head flatly touches the connector (Figure 6). When removing, inspect the connector internally, and ensure there are no polymer chips between the threads (Figure 7).

Figure 6.

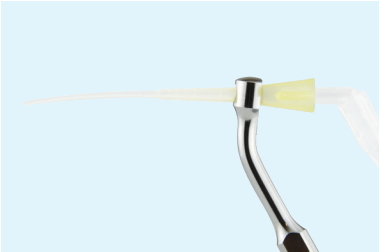


Figure 7.



b. The iVac tip must be positioned apically at the working length to take advantage of negative pressure benefits. A .04 taper preparation will allow the proper insertion of the iVac tip, which has a .025 taper, facilitating fluid flow from the coronal to the apical region. Preparations up to an (ISO) 35 .04 file are suitable for use with the iVac .35 tip (green), and preparations up to an (ISO) 50 .04 file are ideal for the iVac .50 tip (yellow).

6.6. Take the long tube. Pick up the end with a male connector. Connect the male connector to the short tube's female connector (Figure 8). Next, install the low vac adaptor on the low vacuum terminal outlet (Figure 9). Finally, connect the other end of the long tube (female connector) to the adaptor (Figure 10).



Figure 8.

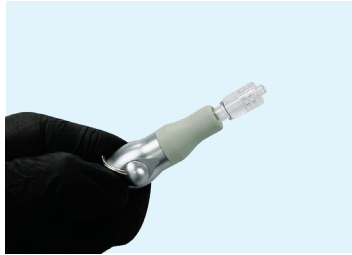


Figure 9.

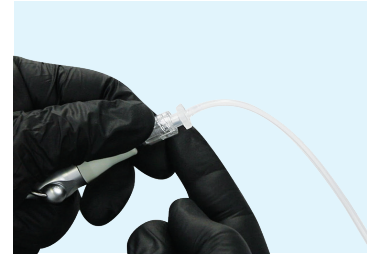


Figure 10.

i **IMPORTANT:**

- If the operator finds the tube too long, remove one of the connectors, trim the tube to the desired length and reinstall the connector.

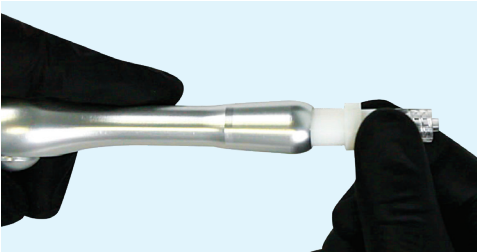


Figure 11.

6.7. **In case a piezo ultrasonic device is used with a reservoir/bottle for concomitant irrigation:**

install the high vac adaptor on the high vac terminal for additional suction at the pulp chamber level. Connect the angled capillary tip (O.D. 0.60mm) to the high vac adaptor (Figure 11).

6.8. **In case a piezo ultrasonic device is used without a reservoir/bottle for concomitant irrigation (syringe and cannula must be used for irrigation):**

connect one angled capillary tip to a 10cc syringe (not included) filled with the preferred solution (sodium hypochlorite, EDTA or distilled water). Install the high vac adaptor on the high vac terminal for additional suction at the pulp chamber level. Connect another angled capillary tip (or another suction tip of your choice) to the high vac adaptor (Figure 11).

7. Piezo ultrasonic device operation setup

i IMPORTANT:

- Operational guidelines can differ depending on the piezo ultrasonic device brand and model.
- Consult your piezo ultrasonic device's instruction manual to set up operating parameters in endodontic mode, seventy percent power (amplitude of vibration), "reservoir/bottle irrigation", or "no-irrigation mode".
- The images used in these instructions were performed using the iVac (Pac-Dent) LED Piezo Ultrasonic device.

! WARNINGS:

- The iVac tips are made of polymer **sensitive to high temperatures**. Therefore, they **deform by melting** due to the sudden connector temperature increase when used at a high power setting without irrigation. Depending on the manufacturer or the time of use of the piezo ultrasonic handpiece/device, discrepancies in power may be noticed. In addition, some equipment may have the wrong resonance for the iVac ultrasonic connector. If there is uncertainty about the best power setting, perform a test starting with seventy percent potency before beginning the procedure. **Accomplish the test using irrigation** from the reservoir or a syringe and cannula. If distortion at the iVac tip is noticed, reduce the power until extended deformation ceases.
- The activation of the iVac tip during the clinical procedure should always be done **with irrigation and with the iVac tip positioned inside the canal**, at the middle third level, or beyond.

i IMPORTANT:

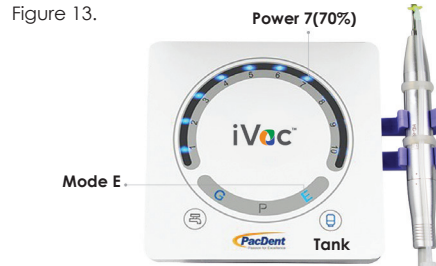
- The manufacturer recommends using the iVac™ LED Piezo Ultrasonic Scaler (Pac-Dent) with the iVac system.

Using the iVac with concomitant irrigation from the piezo ultrasonic reservoir (tank or bottles)

7.1. Fill the tank with the desired fluid (sodium hypochlorite 2% or less, EDTA, or distilled water). If your device has the bottle option, use the chosen irrigant bottle (Figure 12).



7.2. Choose the E frequency to set the piezo ultrasonic unit to the iVac. Ensure the equipment is set to the "reservoir" option. Choose power seven, or seventy percent of maximum power (Figure 13).



7.3. Determine the desired volume of irrigation using the fluid volume control knob (Figure 14). Test the irrigant volume before starting the procedure using a disposable plastic cup or container (Figure 15).



Figure 14.

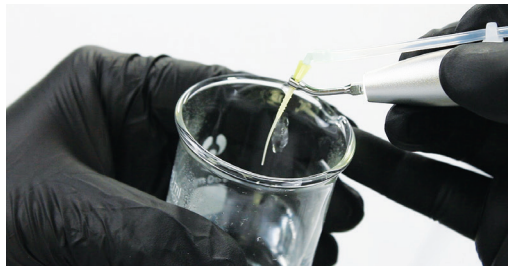


Figure 15.

7.4. Use the angled capillary tip connected to the high vac adaptor for additional evacuation at the pulp chamber during the procedure.



IMPORTANT:

- Typically, the irrigation volume exceeds the iVac 0.35 tips 27mm (green) aspiration capacity. Use the angled capillary tip connected to the high vac connector to evacuate the excess liquid.



WARNINGS:

- a. There is a delay of approximately one minute (depending on the piezo ultrasonic equipment brand and irrigation volume chosen) in exchanging fluids from the reservoir (or bottles). This delay is due to the remaining irrigation fluid in the device tubing, which connects the reservoir to the handpiece.
- b. The piezo device and iVac tubing must be purged after using irrigating fluids, especially sodium hypochlorite. After finishing the operating session, perform the purge cycle (flush) as determined by the piezo ultrasonic unit instruction manual. Always use distilled water to complete the purge cycle. Keep the iVac connector installed to remove fluid traces.

Using the iVac with concomitant irrigation using a syringe and cannula (no tank or bottle irrigation from the piezo ultrasonic device)

7.5. Choose the E frequency to set the piezo ultrasonic unit to the iVac. Ensure the equipment is set to "no-irrigation" option. Next, choose power seven, or seventy percent of maximum power (Figure 16).

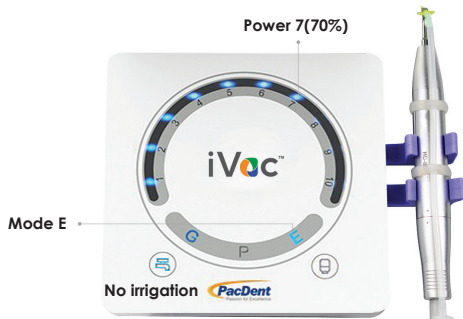


Figure 16.

i IMPORTANT:

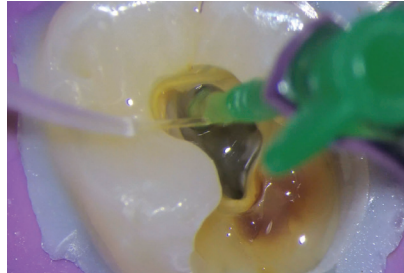
- Consult your piezo ultrasonic device's instruction manual to set up operating parameters in "endodontic mode" (E), seventy percent power (amplitude of vibration), "reservoir/bottle irrigation", or "no-irrigation" mode.
- The images used in this instructions manual were performed using the **iVac™** (Pac-Dent) LED Piezo Ultrasonic Scaler.

! WARNINGS:

- a. The iVac tips are made of polymer **sensitive to high temperatures**. Therefore, they **deform by melting** due to the sudden connector temperature increase when used at a high power setting without irrigation. Depending on the manufacturer or the time of use of the piezo ultrasonic handpiece/device, discrepancies in power may be noticed. In addition, some equipment may have the wrong resonance for the iVac ultrasonic connector. If there is uncertainty about the best power setting, perform a test starting with seventy percent potency before beginning the procedure. **Accomplish the test using irrigation** from the reservoir or a syringe and cannula. If distortion at the iVac tip is noticed, reduce the power until extended deformation ceases.
- b. The activation of the iVac tip during the clinical procedure should always be done **with irrigation and with the iVac tip positioned inside the canal**, at the middle third level, or beyond.

7.6. Use the angled capillary tip attached to a 10cc syringe (not included) filled with the chosen irrigating fluid. Perform **irrigation at the pulp chamber level** (Figure 17), controlling the pressure to avoid liquid overflow.

Figure 17.



7.7. To prevent overflow at the pulp chamber level, use another angled capillary tip connected to the high vac adaptor for additional evacuation at the pulp chamber during the procedure.



IMPORTANT:

- a. Gripping the syringe plunger with the palm of the hand rather than with the thumb will reduce hand fatigue.
- b. Typically, the irrigation volume exceeds the iVac .35 (green) aspiration capacity. Use the angled capillary tip connected to the high vac connector to evacuate the excess liquid.

8. Important clinical considerations



IMPORTANT:

- Although the iVac can be used during the instrumentation phase, its best performance will be achieved before obturation in the final irrigation phase. If the operator desires to use it during instrumentation, use the iVac .50 tip. Use a depth length that keeps the tip free, preventing it from being blocked against the canal walls. In these cases, there will be a **high probability of clogging** due to debris (see section 9. **Clogging**).

8.1. Always ultrasonically activate the iVac tip **inside the canal and under constant irrigation** (Figure 18).

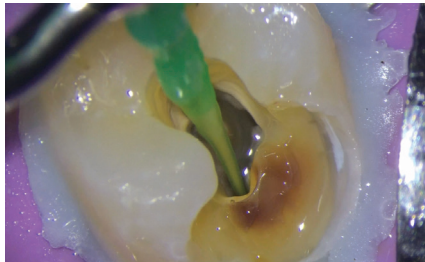


Figure 18.

8.2. For feasible concomitant irrigation with the iVac, the pulp chamber must act as a tank to receive the irrigating fluid from the exit port located at the connector or from a syringe and cannula in manual irrigation. If the crown is compromised, create a temporary crown using a composite restorative material.

8.3. Ensure that the iVac evacuation valve is open during the procedure.

8.4. If the amount of irrigation is greater than the suction capacity of the cannula, proceed with auxiliary suction at the level of the access opening.

8.5. In cases where better irrigation control is desired or when using a piezo ultrasonic device without a reservoir, a syringe and cannula can be used for simultaneous manual irrigation.

8.6. In cases of maxillary teeth, use the fluid volume control of the piezo ultrasonic device to ensure that the irrigant reaches the pulp chamber. If the problem persists, use a syringe and cannula.

8.7. The iVac tip must be positioned apically at 0.5 to 1mm short of the working length to take advantage of negative pressure benefits. A .04 taper preparation will permit the insertion of the iVac tip, which has A .025 taper, facilitating fluid flow from the coronal to the apical

region. Preparations of up to a minimum of (ISO) .35 .04 file are suitable for use with the iVac .35 (green) tip, and preparations of up to a minimum of (ISO) .50 .04 file are ideal for the iVac .50 (yellow) tip.

8.8. Use the depth marks (18, 19, 20, and 23mm) to control the tip insertion. Optionally, a fine-point tip marker can be used.

8.9. To dry the canal before obturation, turn **off vibration, stop irrigation** and keep the vacuum on. Use the iVac tip, vacuum at the working length for at least 3 seconds, and conclude with paper points.



IMPORTANT:

- a. As per Endodontic Standards of Care, **always use rubber dam isolation when performing endodontic treatment.**
- b. The "irrigation/aspiration/activation" modes provided by the iVac can be very advantageous in clinical cases (i.e., apexification, apical resorptions, regenerative cases) where additional care is needed due to the possible extrusion of the irrigating fluid.



WARNINGS:

- Failure to achieve irrigation/aspiration can occur if the iVac tip is taken past the foramen.

9. Clogging

Despite being relatively uncommon, the iVac tip can clog during use. The ultrasonic vibration and the tip's inner diameter reduces clogging chances. However, if it clogs, disconnect the end of the short tube from the long tube. Next, connect the short tube's female connector to a Luer-Lock syringe with water (Figure 19). Press the syringe's plunger gently until water comes out of the tip of the cannula.

Figure 19.



IMPORTANT:

- In anticipation of excessive clogging during **retreatment**, adequate clearing of the canal before using the iVac reduces the chances of tip clogging.

10. Technical specs (tips)

iVac .35 tip

- Color: **green**
- O.D.: **0.35mm (± 0.02)**
- I.D.: **0.15mm (± 0.02)**
- Taper (D_0 - D_{16}): **0.025 (± 0.05) [$D_0=35$; $D_{16}=75$]**
- Total length: **30mm**
- Working length: **27mm**
- Depth marks at 18, 19, 20, and 23mm

iVac .50 tip

- Color: **yellow**
- O.D.: **0.50mm (± 0.02)**
- I.D.: **0.30mm (± 0.02)**
- Taper (D_0 - D_{16}): **0.025 (± 0.05) [$D_0=50$; $D_{16}=90$]**
- Total length: **30mm**
- Working length: **27mm**
- Depth marks at 18, 19, 20, and 23mm

Angled capillary tip

- O.D.: **0.60mm (± 0.05)**
- I.D.: **0.30mm (± 0.05)**
- Working length (after angle): **21mm**

11. Cleaning and sterilization



WARNINGS:

- All parts are not sterile. Sterilize all components before first use.
- All reusable components (long tube, short tube, low vac adaptor, high vac adaptor, and rings) must be cleaned and sterilized before use. In addition, it is recommended to sterilize reusable components for **a maximum of 5 cycles**. The **iVac connector** can be used and re-sterilized until any damage or deformation is perceived.
- iVac tips are single-use parts. Sterilize before use. Discard after use.**
- iVac S and E-type connectors are not disposable and are reusable. Clean and sterilize before use. Replace the connector if there are any signs of discoloration, wear, or damage.
- Failure to properly clean the components could lead to inadequate sterilization.
- Only use cleaning solutions tested for efficacy and compatibility with the device/equipment.
- Always observe all applicable legal and hygiene regulations for the practice and/or hospital.
- Always wear protective gloves, glasses, and a mask when handling contaminated instruments.
- Replace the reusable components (long tube, low vac adaptor, high vac adaptor, and rings) if there are any signs of discoloration, wear, damage, or after 5 sterilization cycles.
- Cold liquid disinfection/sterilization, chemical vapor sterilization, and dry heat sterilization methods have not been tested or validated for efficacy and are not recommended.

Manual cleaning

- 11.1. Use hospital-grade enzymatic detergent. Follow manufacturer instructions for cleaning detergent concentration.
- 11.2. Soak the reusable parts in detergent for 15 minutes.
- 11.3. Remove debris with cleaning detergent by scrubbing all external surfaces with a soft bristle brush until all visible debris has been removed.
- 11.4. Use a small diameter brush or pipe cleaner to clean cannulation holes.
- 11.5. All exposed surfaces should be free of visible debris.
- 11.6. After cleaning, rinse the parts under warm running water for 3 minutes.
- 11.7. Pay special attention to rinsing all holes and lumens.
- 11.8. Air dry in a clean area. Blow lumens with clean air using a filtered air source.



WARNINGS:

- a. Inspect to ensure all visible contamination has been removed.
- b. Check for damage and wear: corrosion, discoloration, or cracking.
- c. Discard damaged or corroded components. If not visibly clean, repeat the process or dispose of components.

Packing

- 11.9. Place product in a single F.D.A. cleared sterilization pouch.
- 11.10. Ensure the pouch is large enough to contain the components without stressing the seals.

Sterilization

- 11.11. Pre-vacuum Steam Sterilization.
- 11.12. Full autoclave cycle: Wrapped at 134°C (273°F) for 4 minutes, with a dry time of 20 minutes.
Full autoclave cycle: Wrapped at 121°C (250°F) for 30 minutes, with a dry time of 15 minutes.

**CAUTION:**

- a. When sterilizing multiple instruments in one autoclave cycle, ensure that the sterilizer's maximum load is not exceeded.
- b. To maintain sterility, instruments should remain wrapped until ready for use.

**IMPORTANT:**

- The instructions provided have been validated by the medical device's manufacturer as capable of preparing some parts for reuse. However, it remains the processor's responsibility to ensure that the reprocessing is performed using equipment, materials, and personnel in the reprocessing facility to fully achieve the desired result. This requires validation and routine monitoring of the process.

12. Symbols

	Trademark		Important information or explanations intended for users. Notes		F.D.A. Food and Drug Administration (U.S.) marked the product
	Date of manufacture		A hazardous situation that can cause material damage		Atmospheric pressure for storage
	Non-sterile		Do not use near patients with pacemakers		Temperature limitation for storage
	Manufacturer for		Sterilizable up to the temperature		On-line instructions
	Follow instructions for use		Warning and precautions		Keep dry

13. Statement

13.1. Pac-Dent, its representatives, and its distributors/dealers shall have no liability or responsibility to customers or any other person or entity concerning any liability, loss, or damage caused or alleged to be caused directly or indirectly by the medical device sold or furnished by us, including, but not limited to, any interruption of service, loss of business or anticipatory profits, or consequential damages resulting from the use or operation of the equipment.

13.2. Pac-Dent assumes no liability resulting from improper use, damage, or breakage due to misuse of these components by the purchaser. Likewise, **Pac-Dent** assumes no liability for damage to the iVac™ system components, injuries to patients or users, or other problems resulting from improper use of accessories or other materials not supplied by **Pac-Dent**.

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13.4. Patent pending. U.S. Patent No. 63221851. U.S. Patent and Trademark Office, 2021.



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