PacDent
Passion for Excellence

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

iVac™

Apical Negative Pressure Irrigation and Activation Kit

Contents

1. Introduction

Thanks for purchasing the **iVac™ Apical Negative Pressure Irrigation and Activation 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 scaler device recurrently mentioned in these instructions for use is not included with the introductory kit.

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 introductory kit parts should be used with the same type of ultrasonic connector and piezo ultrasonic handpiece (S-type [M3,0 x 0,6 AG] or E-type [M3,0 x 0.5 AG]). Consult your piezo ultrasonic device instructions about the insert's compatibility **(S or E-type).** Do not try to install the E-type ultrasonic connector on an S-type piezo ultrasonic handpiece. Likewise, do not try to install the S-type ultrasonic connector on an E-type piezo ultrasonic handpiece. Both situations damage the handpiece permanently.

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#9542SIVC/REF#9542EIVC) Contents:

- 5 x 0.35 iVac tips 27mm
- 5 x 0.50 iVac tips 27mm
- 10 x Angled capillary tips
- 10 x Rings
- 5 x Short silicone tubing with 1 female connector and 1 elbow connector
- 5 x Low Vac adaptor
- 1 x Technique Guide
- 5 x Long silicone tubing with 1 female connector and 1 male connector
- 5 x High Vac adaptor
- 1 x Instructions for Use
- 5 x iVac S-type piezo connector(REF#9542SIVC)/5 x iVac E-type piezo connector(REF#9542EIVC)

The iVac™ system Refill kit components:

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

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

REF#	Description	Figure	Usage cycle
9542ACT	10x Angled capillary tips 0.65mm		Single-use. Sterilize before use.
9542ST	5x Short (170mm) silicone tubing with 1 female connector and 1 elbow connector		Single-use. Sterilize before use.
9542R	10x Rings		Single-use. Sterilize before use.

IMPORTANT:

• The iVac system should preferably be used with a piezo ultrasonic device. The introductory kit **includes an S or E-type iVac piezo connector.** The piezo ultrasonic handpiece connected with the iVac ultrasonic connector must be the same type, S-type (M3,0 x 0,6 AG) or E-type (M3,0 x 0.5 AG).

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		Single-use. Sterilize before use.
	1x Low Vac-adaptor		Single-use. Sterilize before use.
	1x High Vac-adaptor		Single-use. Sterilize before use.

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 fundaments 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. Only use the iVac piezo connector on piezo ultrasonic devices that use the same type of threading (S or E-type). Placing the iVac piezo 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 2.5% concentration.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**.

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 piezo ultrasonic handpiece connected with the iVac ultrasonic connector must be the same type.Use the iVac S-type connector (REF#9542SC) or the iVac E-type connector (REF#9542EC) depending on the pizeo type (S or E-type).

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

IMPORTANT:

•The piezo ultrasonic device currently mentioned in these instructions for use is not included with the intro 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.

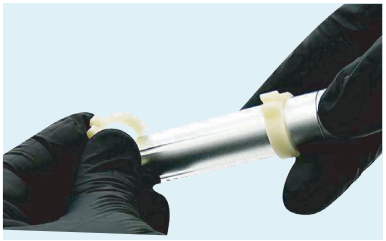


Figure 1.

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 connector and install it on the same type handpiece. Start screwing it with your fingers in a clockwise motion.

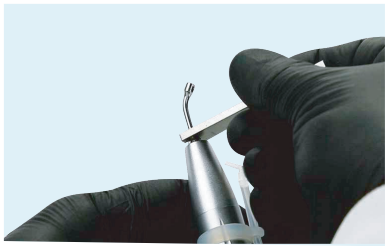
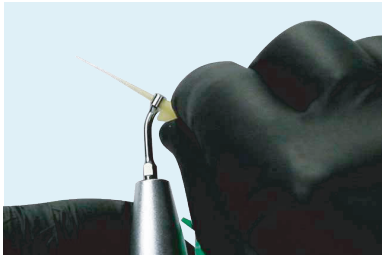


Figure 3.

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.



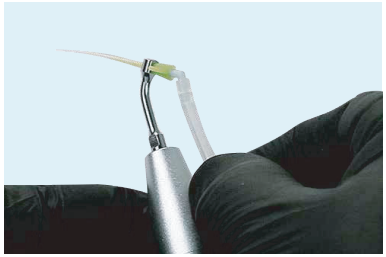


Figure 5.

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.

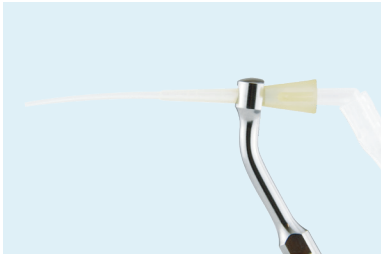


Figure 7.

b. The iVac tip must be positioned as close to the working length as possible. The operator should release 0.5 mm in cases of apical resistance, preventing the tip from collapsing. A .04 taper preparation allows a proper insertion of the iVac tip, which has 0.25 taper, facilitating fluid flow from the coronal to the apical third. Preparations to (ISO) 35 .04 or even (ISO) 25 .06 are suitable for final irrigation protocol use with the 0.35 tips. The iVac .50 can be used during the instrumentation phase and for the final irrigation protocol in preparations (ISO) 50 or higher.

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.

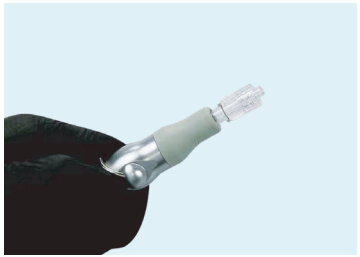


Figure 9.

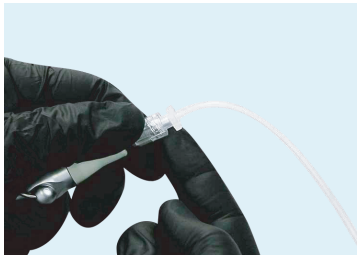


Figure 10.

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.

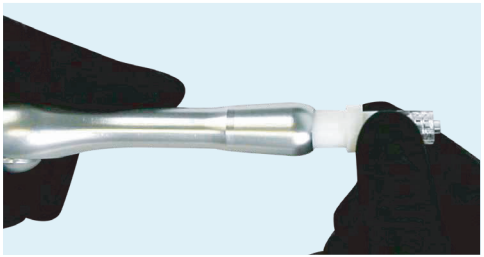


Figure 11.

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. 0.65mm) 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

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".

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 twenty 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.

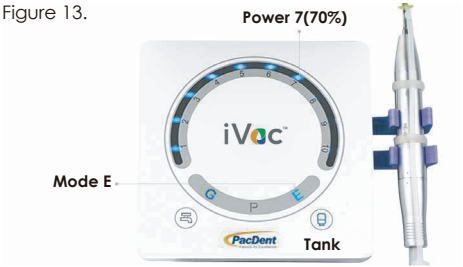
Using the iVac with concomitant irrigation from the piezo ultrasonic reservoir (tank or bottles)

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).

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).

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). **Choose the minimal power 1 (10%) to perform the irrigant volume test.**

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:

- 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.

- 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 pizeo 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).

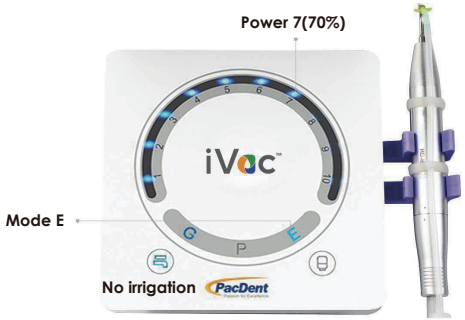


Figure 16.

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.

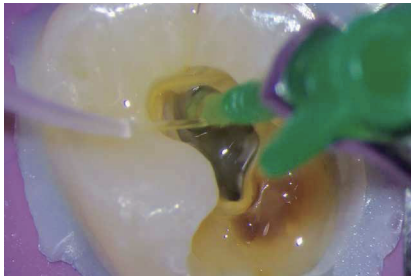
WARNINGS:

- 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.

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.

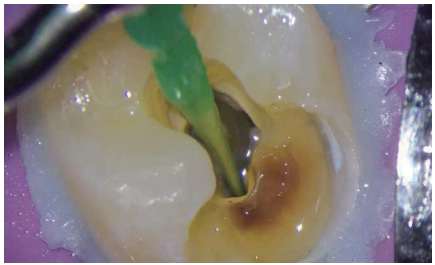
8. Important clinical considerations

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***
- I.D.: ***0.15mm***
- Taper (D_0-D_{16}): ***0.025[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***
- I.D.: ***0.30mm***
- Taper (D_0-D_{16}): ***0.025[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.: ***0.65mm***
- I.D.: ***0.30mm***
- Working length (after angle): ***21mm***

11. Cleaning and sterilization

WARNINGS:

- All parts are single-use parts. Sterilize before use. Discard after use.
- 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.
- Cold liquid disinfection/sterilization, chemical vapor sterilization, and dry heat sterilization methods have not been tested or validatedfor efficacy and are not recommended.

IMPORTANT:

11.1 Automated cleaning. Automated disinfection with washer-disinfector.

- The washer-disinfector is proved to be valid by CE certification in accordance with EN ISO 15883.
- The disinfection cycle is in accordance with the disinfection cycle in EN ISO 15883.

11.2. Cleaning and disinfecting steps by using washer-disinfector.

- All components must be reprocessed in a disassembled state, as far as possible.
- Before use, you must carefully read the operating instructions provided by the equipment manufacturer to familiarize yourself with the disinfection process and precautions.
- With this equipment, cleaning, disinfection and drying will be carried out together.

11.2.1 Pre-Cleaning:

- Prior to automated processing of the 0.35 iVac tips 27mm, 0.50 iVac tips 27mm and angled capillary tips, ensure that the lumen of the tip is "open" and unclogged. Connect a syringe to the tip via Luer-Lock connector. Inject water into the tip lumen to ensure the patency of the tip. If the patency of the tip cannot be ensured, do not process the tip.
- Usually, no manual pre-cleaning is required for the other components. In case of heavy contamination, submerge the products in a cleaning solution and clean the surfaces with a soft bristle brush.

11.2.2 Cleaning:

Connect the tips to the WD via Luer-Lock connector as per the WD manufacturer's instructions.
For other components, put the device into the machine on a tray. The products in the washer-disinfector are arranged in such a way that there is no rinsing shadow and the water drains off quickly. Start the program:

- 4 min pre-washing with cold water (<40°C);
- Emptying;
- 5 min washing with a mild alkaline cleaner at 55°C;
- Emptying;
- 3 min neutralising with warm water (>40°C);
- Emptying;
- 5 min intermediate rinsing with warm water (>40°C);
- Emptying.

During the use of cleaner, the concentration, temperature and time provided by manufacturer shall be obeyed. The automated cleaning processes have been validated by using 0.5% neodisher MediClean forte (Dr. Weigert).

Note:

Acc. to EN ISO 17664 no manual processing methods are required for these devices. If a manual processing method has to be used, please validate it prior to use.

11.2.3 Disinfection:

- Automated Thermal Disinfection in washer/disinfector under consideration of national requirements in regards to A0 value (see EN 15883).
- A disinfection cycle of 5 min disinfection at 90°C has been validated for the device to achieve an A0 value of > 3000. Here we suggest a disinfection cycle of 5 min disinfection time at 93 °C.

11.2.4 Drying:

- Drying the products through drying cycle of washer/disinfector. If needed, additional manual drying can be performed through lint free towel. Insufflate cavities of products by using sterile compressed air.
- If your cleaning and disinfection process does not have an automatic drying function, dry it after cleaning and disinfection.

Methods:

1.Spread a clean white paper (white cloth) on the flat table, point the product against the white paper (white cloth), and then dry the product with filtered dry compressed air (maximum pressure 3 bar). Until no liquid is sprayed onto the white paper (white cloth), the product drying is completed.

2.It can also be dried directly in a medical drying cabinet (or oven). The recommended drying temperature is 80° - 120° and the time should be 15- 40 minutes.

11.2.5 Functional Testing, Maintenance:

Visual inspection for cleanliness of the products and reassembling, if required.
All products should be checked again for dryness.
After cleaning and disinfection, a thorough inspection and maintenance ensures that the products are fit for use.

- Check that the product has no dents, cracks, deformations, scratches, etc.
- 0.35 iVac tips 27mm, 0.50 iVac tips 27mm and angled capillary tips: check the patency of the lumen.
- Check all markings on the product for clear visibility.

Discard and replace any components as necessary.
Do not use the device with following defects: material deformation, cracks on the product, brittle or other change in the material, etc.

11.3 Packaging

Install the disinfected and dried product and quickly package it in a medical sterilization bag (or special holder, sterile box).

IMPORTANT:

Notes:

a.The package used conforms to ISO 11607;
b.It can withstand high temperature of 138 °C and has sufficient steam permeability;
c.The packaging environment and related tools must be cleaned regularly to ensure cleanliness and prevent the introduction of contaminants;
d.Avoid contact with components of different metals when packaging.

11.4 Sterilization

Sterilization of products by applying a fractionated pre-vacuum steam sterilization process (according to EN 285/EN 13060/EN ISO 17665) under consideration of the respective country requirements.
Following sterilization parameters are commonly used: 134 °C, 5 min (standard program in EU)
Drying time:
For steam sterilization, we recommend a drying time of 20 to 40 minutes. Choose a suitable drying time, depending on the autoclave and load. Refer to the autoclave's instructions for use.
After sterilization:
a.Remove the product from the autoclave.
b.Let the product cool down at room temperature for at least 30 minutes. Do not use additional cooling.
Check that the sterilization wraps or pouches are not damaged.

Notes:

a.Only products that have been effectively cleaned and disinfected are allowed to be sterilized;
b. Before using the sterilizer for sterilization, read the Instruction Manual provided by the equipment manufacturer and follow the instructions.
c. Do not use hot air sterilization and radiation sterilization as this may result in damage to the product;
d. Please use the recommended sterilization procedures for sterilization. It is not recommended to sterilize with other sterilization procedures such as ethylene oxide, formaldehyde and low temperature plasma sterilization. The manufacturer assumes no responsibility for the procedures that have not been recommended. If you use the sterilization procedures that have not been recommended, please adhere to related effective standards and verify the suitability and effectiveness. Fractional pre-vacuum procedure = steam sterilization with repetitive pre-vacuum. The procedure used here is to perform steam sterilization through three pre-vacuums.

11.5 Storage

1.Store in a clean, dry, ventilated, non-corrosive atmosphere with a relative humidity of 10% to 93%, an atmospheric pressure of 70KPa to 106KPa, and a temperature of -20 °C to +55 °C;
2.After sterilization,the product should be packaged in a medical sterilization bag or a clean sealing container, and stored in a special storage cabinet. The storage time should not exceed 7 days. If it is exceeded, it should be reprocessed before use.

Notes:

a.The storage environment should be clean and must be disinfected regularly;
b.Product storage must be batched and marked and recorded.

11.6 Transportation

1. Prevent excessive shock and vibration during transportation, and handle with care;
2. It should not be mixed with dangerous goods during transportation.
3. Avoid exposure to sun or rain or snow during transportation.

12. Symbols

iVac™	Trademark		Important information or explanations intended for users. Notes		Keep away from sunlight
	Date of manufacture	CAUTION	A hazardous situation that can cause material damage		Keep Dry
	Manufacturer		Do not use near patients with pacemakers	MD	Medical Device
	Do not re-use	134°C	Sterilizable up to the temperature	EC REP	Authorized representative in the European Community/ European Union
	Consult Instructions for Use	WARNING	Warning and precautions	55°C 131°F -20°C -4°F	Temperature limit
NON STERILE	Non-sterile		Atmospheric pressure limitation	CE	CE marking

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**.

13.3. Pac-Dent reserves the right to implement changes and modifications of the product, revise this publication and make changes in the contents hereof without obligation to notify any person of such changes, modifications, or revisions. All rights to modify the product are reserved for **Pac-Dent** without further notice. The pictures are only for reference. Industrial design, inner structure, etc., have been claimed by several patents.

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

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