



Premium AirSonic SURGERY

Pneumatic handpiece

Operating Instruction



Only for USA
Caution! Federal Law restricts this device to sale by or on the order of a dentist, physician or any other practitioner licensed by the law of the State in which he or she practices to use or order the use of the device.

■ Introduction

Dear User
Congratulations on purchasing this Jindell Quality product as your professional tool. This device is designed for dental treatment purpose. By following the instructions below, you will be able to work smoothly, economically and safely.

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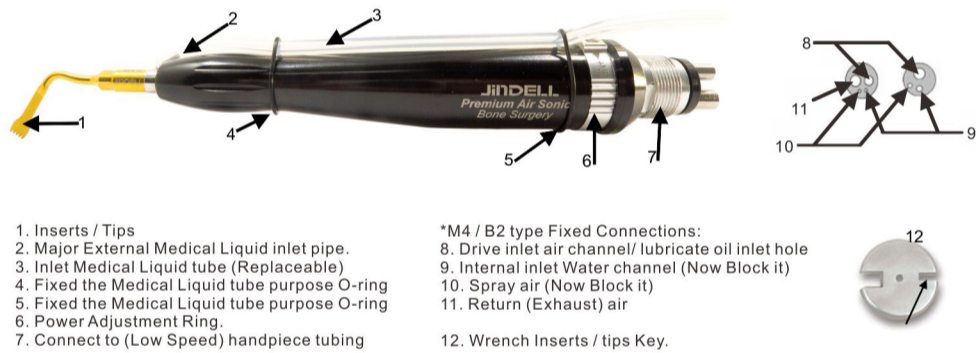
- Symbols:**
- Refer to the chapter on Safety/ Warning symbol
 - Important information for users and service technicians
 - Thermo washer Disinfectable
 - Can be steam- sterilized at 134°C -1°C/ +4°C (273°F -1.6°F/ +7.4°F)

CE This Medical Device production meets the requirements of the applicable EU directive 93/42/EEC & 2007/47/EC.

■ Disclaimer

- The Jindell Company will not be responsible for accidents, equipment damage, or bodily injury resulting from:
- repairs made by personal not authorized by the Jindell Company
 - any changes, modifications, or alterations of its products
 - the use of products or equipment made by the other manufacturers, except for those procures by the Jindell Company
 - maintenance or repairs using parts or components other than those specified by the jindell company and other than in the original condition
 - operating the equipment in ways other than the operating procedures described in the manual or resulting from the safety precautions and warnings in this manual not being observed
 - workplace conditions and environment or installation conditions which do not conform to those stated in this manual such as improper electrical power supply
 - fires, earthquakes, flood, lightning, natural disasters, or acts of God
- The Jindell Company will supply replacement parts and be able to repair the product for a period of 10 years after the manufacture of the product has been discontinued.
- Warranty is honored only when a claim is accompanied by the warranty agreement with purchase date, product name and model, serial number (inscribed on the body of the product) and name of the distributor.
- Products are subjected to change without notice.

■ Product Description



- Inserts / Tips
- Major External Medical Liquid inlet pipe.
- Inlet Medical Liquid tube (Replaceable)
- Fixed the Medical Liquid tube purpose O-ring
- Fixed the Medical Liquid tube purpose O-ring
- Power Adjustment Ring.
- Connect to (Low Speed) handpiece tubing
- *M4 / B2 type Fixed Connections:
- Drive inlet air channel/ lubricate oil inlet hole
- Internal inlet Water channel (Now Block it)
- Spray air (Now Block it)
- Return (Exhaust) air
- Wrench Inserts / tips Key.

■ Technical data

Drive Condition	■ Drive Air Pressure: 2.2 – 3.5 bar (31 – 50 psi) ■ Medical Liquid: 0.8 – 2.5 bar (12–36 psi) ■ Return air: < 0.5 bar (7 psi)
Recommend Condition	■ Drive Air Pressure: 2.5 bar (2.54 kg/ cm², 36 psi) ■ Medical Liquid supply flow volume> 50ml/min (@2.0 bar)
Air Consumption	18– 50 NL/min

*The device is a dental handpiece in accordance with ISO 15606. In combination with the different Jindell Inserts/ tips, an oscillating elliptical tip motion is generated for the respective application. The External water cooling (spray cooling) prevents the treatment field from heating up, and keeps the treatment surface clean.

*The device should be operated with the described operating pressure. After starting, the intensity can be regulated using the foot switch at maximum drive pressure.

■ Transportation and storage condition

Prior to start-up, very cold products must be heated to a temperature of 20 °C to 25 °C (68 °F to 77 °F). Otherwise it can cause the medical device to malfunction.

DO NOT STORE THIS DEVICE IN EXCESSIVELY COLD LOCATION

Storage conditions:
Surrounding Temperature from -20°C (-4°F) to +70°C (+158°F); Atmospheric pressure from 700hPa to 1060hPa (10 to 15 psi); Relative humidity from 5%RH to 95%RH absence of condensation



- Caution**
- The device is not supplied sterile condition before shipping. It must be autoclaved or sterilized before first use and after each use.
 - The tips may break from continuous stress or damage (such as being dropped on the floor or being bent). Therefore, check the tip to see if it is safe before each use by applying a slight amount of pressure with your thumb or index finger.
 - Do not exceed the recommended air pressure at the back end of the device. Excessive air pressure might cause the device tip to accidentally break while in use.
 - A supply of dry, clean, cooling and contamination-free compressed air according to EN ISO 7494- 2 must be provided.
 - The handpiece must use Select the right type of insert/ tip according to the operation to be performed and screw it manually onto the handpiece. The insert must then be moderately tightened using the supplied key. Inserts must always be removed after use.
 - The sterilization parameters must correspond with those of the Pharmacopoeia Official. (ex.: 121°C/ 134°C)
 - Proper cleaning& lubrication before sterilizations is essential to prevent the build-up of debris.
 - The handpiece of fastening to the handpiece tubing (hose) or connector must meet the standard of ISO 9168 Type A.
 - Infected and humid cooling compressed air will result in malfunctions and lead to premature bearing wear.
 - Do not attempt to disassemble the handpiece nor tamper with the mechanism.
 - Do not use Dry-Heat sterilization; it will result in malfunctions and lead to premature bearing wear.
 - Do not use wire brush to clean the handpiece sheath. Wipe clean with alcohol-immersed cloth or cotton swab.
 - Do not immerse handpiece in disinfectant solution or boiling water, acidic water or acidic solutions, nor chemicals, and not to be cleaned by ultrasonic cleaning bath device process.
 - Avoid crashing the handpiece. Take care not to drop the handpiece as it may cause serious damage and void the warranty. Be carefully!
 - The oscillation of the tip could exceed 200µm amplitude at the recommended air pressure. Caution is requested not to harm the patient
 - Do not use a tip on which rust is found. It may break while in use at where rust grew.
 - Check for vibration, noise and overheating outside the patient's oral cavity before use. If any abnormalities are found, stop using the handpiece immediately. Contact your authorized Jindell Dealer for service.
 - Before each use, check if the handpiece is securely locked onto the tubing (hose) by pulling on it.
 - Daily maintenance procedure will be recommended: step 1 is remove the handpiece from the handpiece tubing (hose), step 2 is remove the Insert/ Tips, step 3 is scrub handpiece under running water with soft sponge or clothe to remove external debris, step 4 is lubrication, final is Sterilization.
 - Operators and all others in the area must wear eye protection when operating this handpiece
 - Must the handpiece not function normally, cease operation immediately and return the handpiece to your authorized Jindell Dealer for service.

■ Installation

- Connect to the Units:**
- Connect the AirSonic handpiece to the Handpiece tube (hose). In case the supply air pressure at the connection (where the device is connected to the handpiece hose) is set at the recommended 0.3MPa(3.0kgf/cm2), the device is ready usable.
 - Set the supply air pressure at 03 MPa (3.0kgf/cm²) at the connection where the device is connected to the handpiece hose, as shown by the arrow in Fig.1.
 - Screw the back-end fixed connection type handpiece onto the tubing (hose) and tighten firmly.

- Fig. 1**
- Higher air pressure may cause higher tip oscillation, which could damage the tooth surface and may cause pain to the patient. It also may shoten the tip life and premature failure or breakage of the tip.
 - The amplitude may exceed 200µm, even at the recommended air pressure, care should be exercised not to harm the patient.

- Checking the pressure:**
- Recommended pressure is 2.5 bar (36 psi).
 - Moisture and debris in drive air may cause the device to malfunction. It is important to drain the air compressor on a regular basis, even though an air filter or air drying device is provided in the air line.

- Checking the amount of water:**
- Adjust the water volume for the coolant to 50 ml/ min (cm³/min) or 3.1 inch³/ min above.
 - At the beginning of each workday, the water-conducting systems should be rinsed for at least 2 min. without the instrument being attached; if there is a risk of contamination from reflux or back suction, the system must be rinsed for 20-30 seconds.

■ To Change the Inserts / Tips

Select the right type of insert according to the operation to be performed and screw it manually onto the handpiece. The inserts / tips must then be moderately tightened using the supplied wrench Inserts / Tips key.

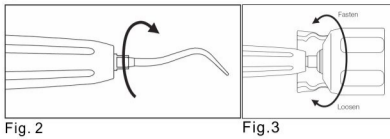
Wrench Inserts/ Tips Key

Installation the Inserts / Tips :

- Screw via the wrench key in the insert/ tip until ?nger tight. (Fig.2) Mount the supplied wrench tool over the tip, and align the square holes to mate with counterpart on the tip. Turn the wrench ?rmly until two or three clicks are heard. (Fig.3) The clicking, or tripping, takes place when the turning force exceeds the preset value. This wrench fastens the tip at the preset consistent force at all times.

Removal the Inserts / Tips :

- Mount the wrench over the insert/ tip and turn it in the direction as shown in Fig.3.

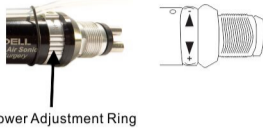


Caution

- Always use the wrench to securely tighten the insert/ tip. Loose tip may come off during use and cause injury.
- Inserts/ Tips must always be removed after use.
- Do not fit inserts/ Tips while the handpiece is running.
- The shape and weight of each insert are the result of a precise design optimization so as to obtain maximum performance. Therefore, any alteration, breaking, twisting or wearing of the insert can cause abnormal operation: in such case it is strongly recommended that the insert be replaced.
- Do not use such tips as shown below. Tips are expendable items.
- Insert/ Tips with worn and dull edges.
- Corroded or rusted insert/ tips.
- Deformed tips, as caused by impact or fall.
- Do not grind or polish for reuse.
- Watch out the sharp point.

■ Power Adjustment

- Power may be increased or decreased by rotating the ring nut located at the bottom of the handpiece.
- Close the handpiece Power Adjustment ring by turning it in the sense of the "+" arrow.
- Completely press the foot control of the air supply.
- Gradually open the air supply by gently turning the Power Adjustment ring in the sense of the "+" arrow.
- The handpiece is well turned when the tip discontinues moving when your finger touches its flute.
- Release the foot control before the Surgery treatment.



■ Lubrication:

- In order for the instrument you have purchased to be helpful in your profession for a very long time, carefully repeat the following operation weekly.
- Remove the Inserts/ Tips first.
- Turn the handpiece Power Adjustment ring in the sense of the "+" arrow
- Detach the handpiece from the supply hose and lubricate using the spray can into the handpiece's air admission hole and press the spray lasting two seconds, until the characteristic hissing sound can be heard.
- Make the handpiece turn in order to evacuate excess oil before use.
- During long treatments, repeat the lubrication process every ten minutes.
- For the M4 (4 hole) / B2 (2 hole) type backend fixed connection handpiece; supply 2- 3 drops of oil into the drive air tube or hole of the handpiece once or twice a day. (Fig.4) Operate the handpiece for 15- 20 seconds to remove residual debris and oil. Lubricate at least twice a day.
- Only high quality lubricants recommended for use with dental instruments must be used.
- Always cleaning& lubricate before sterilization!



■ Hygienic Maintenance& Cleaning:

- Follow your country-specific directives, standards and guidelines for cleaning, disinfection and sterilization.
- Daily maintenance the turbine handpiece manually or mechanically procedure will recommend:
- step 1: Wear protective clothing & remove the handpiece from the swivel coupler or handpiece tubing (hose),
 - step 2: remove the Insert / tip
 - step 3: Scrub handpiece under flowing tap water (30 °C ± 5 °C (86 °F ± 10 °F) with soft sponge or cloth or a medium hard toothbrush to remove external debris,
 - step 4: lubrication,
 - final: Sterilization
- Caution**
- Do not immerse handpiece or cartridges/ rotor in disinfectant solution or boiling water, nor chemicals, and not to be cleaned by ultrasonic cleaning bath device process.
 - Only use lubrication maintenance products and/or components approved by spray oil or the automatic cleaning &lubrication device.
 - Manually clean debris off with a brush off the handpiece outside under running water 30°C ± 5°C or clean with 70%- 80% alcohol solution for Disinfection.
 - Wire cleaner may be inserted into exterior spray holes to dislodge any foreign matter and debris. If the blockage is located in the interior portion of the spray tubes, the instrument must be sent to Jindell or an authorized repair facility for repair.

■ Thermo washer Disinfect

Handpiece with this symbol maybe cleaned and disinfected with a thermal washer disinfector.

- To use a thermal washer disinfector, first read the operation instructions for the unit. Strictly follow the instructions attached for cleaning mode of solution
- Jindell recommends thermo washer disinfectors in accordance with EN ISO 15883-1, which are operated with alkaline cleaning agents with a pH value of max. 10 (e.g. Miele G 7781/G 7881 – Validation was carried out with Programme "VARIO-TD", cleaning agent "neodisher® mediclean", neutralisation agent "neodisher® Z" and rinsing agent "neodisher® mielclear" and only applies to the material compatibility with Jindell products).
 - For program settings as well as cleansers and disinfectants to be used, please refer to the Instructions for Use of the thermo washer disinfector (complying with max. pH value of 10).
 - Follow the instructions for use of the thermo washer disinfector.

- Caution**
- Do not use Dry-Heat sterilization; it will result in malfunctions and lead to premature bearing wear.
 - Improper cleaning modes and solutions will damage the instrument.
 - Only disinfect in a thermo washer disinfector or manually.
 - Follow the disinfector manufacture's recommendations for cleaning solutions and methods for dental instruments. Do not use strong acidic or alkaline solutions. Thoroughly rinse off all cleaning solution.

■ Sterilization

- Sterilization in a steam sterilizer (autoclave) in accordance with EN 13060 / ISO 17665-1
- The Jindell medical device has a maximum temperature resistance up to 138°C (280.4°F).
- (Depending on the available autoclave,) select a suitable procedure from the following sterilization processes:
- Recommended sterilization methods/parameters for wrapped loads are as follows:
- Autoclave with three times with an pre- vacuum Pressure pulse "S" cycle (According with EN 13060, class S) at least 3 minutes at 134°C -1°C / +4°C (273.2°F -1.6°F / +7.4 °F) and cool at room temperature.

- Autoclave using the gravitation method: at least 10 minutes at 134°C -1°C / +4°C (273.2°F -1.6°F / +7.4 °F) or alternatively at least 60 minutes at 121°C -1°C / +4°C (250°F -1.6°F / +7.4 °F) and cool at room temperature.
- Insert into an autoclave pouch and seal the pouch before Sterilization is recommended according to EN 868-5.
- Follow the steam sterilizer (autoclave) manufacturer's Instructions for Use.

- Caution**
- Do not use Dry-Heat sterilization; it will result in malfunctions and lead to premature bearing wear.
 - Sterilization is recommended by DIN EN 13060 or EN554. Jindell recommended sterilization according to EN 13060, class B (pre & post vacuum).
 - Proper cleaning& lubrication before sterilizations is essential to prevent the build-up of debris & remove the Inserts / Tips
 - Wrap the Handpiece and the accessory in sterile goods packing (autoclave pouch) and seal according to EN 868-5
 - Make sure that you only remove dry sterile goods. & Store sterile goods dust-free and dry.
 - Immediately remove the product from the steam sterilizer after the sterilization cycle will damaged to product!
 - Sterilization is required before the first use and between each patient use to prevent cross- infection.**
 - If the sterilizer chamber temperature must exceed during 135°C (or 275°F) during the drying cycle, then delete the drying cycle.
 - Always place the handpiece in the center or upper shelf of the chamber, as the local temperature at the bottom of the chamber could rise beyond the level indicated on the autoclave.
 - Never heat or cool the handpiece quickly; Rapid change in temperature could damage the glass rod or subject other metals to abnormal stress.
 - Do not wash, soak, or wipe off the handpiece with a Potentially Corrosive Solution (strong acid, super acid solution) or cold sterilization solution.

■ Guarantee:

- The following warranty conditions apply to this Jindell medical device:
- Jindell provides the end customer with a warranty of proper function and guarantees zero defects in respect of material and processing for a period of 6 to 12 months from the date of the invoice, subject to the following conditions:
- In case of justified complaints, Jindell will honor its warranty with a free replacement or repair. Other claims of any nature whatsoever, in particular with respect to compensation, are excluded. In the event of default, gross negligence or intent, this shall only apply in the absence of mandatory legal regulations to the contrary.
- Jindell shall not be liable for defects and their consequences that have arisen or may arise from natural wear, improper handling, cleaning or maintenance, non-compliance with operating, maintenance or connection instructions, calcination or corrosion, contaminated air or water supplies or chemical or electrical factors deemed abnormal or impermissible in accordance with Jindell's instructions for use or other manufacturer's nstructions. The warranty granted does not usually extend to lamps, light conductors made of glass and glass fiber optic, glassware, rubber parts, and the colorfastness of plastic parts.
- All liability is excluded if defects or their consequences originate from manipulations or changes to the product made by the customer or a third party that is not authorized by Jindell.
- Warranty claims will only be accepted if the product is submitted along with proof of purchase in the form of a copy of the invoice or note of delivery. The dealer, purchase date, type, and serial number must be clearly evident from this document.

■ DECALARTION OF CE CONFORMITY

Manufactured/ Distributed by:



Declares under its own responsibility that following products:
Product Name: **Dental AirSonic Handpiece**; Model in the Version: **Premium AirSonic Surgery Series**
It fully conforms to the following ISO 13485, EU directive 93/42/EEC & 2007/47/EC Annex II(Medical Device Directive)

Class which the equipment belongs to: **Ila**
It conforms to the following standards:
-ISO 15606; -ISO 9168; -ISO 1797; -ISO 7494-2; -ISO 14971; -EN 15223-1; -EN 15883-1

※ Specifications maybe changed without notice.

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