

Premium LUX

E11/E15/E16/E20

Contra Angle Handpiece

OPERATION MANUAL



Please read this Operation Manual carefully before use and file for future reference

Introduction

Dear User

- Congratulations on purchasing this Jindell Quality product as your professional tool. This device is designed for dental treatment such as grinding, drilling and polishing teeth purpose. By following the instructions below you will be able to work smoothly, economically and safely.
- This medical device is intended for transmitting rotation of the power source at the direct drive ratio or at a different gear ratio, there by running the instrument such as a bur or a reamer to cut and polish natural or artificial teeth during dental treatment.

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Precautions for handling and operation

- Please read these precautions carefully and use only as intended or instructed.
- Safety instructions are intended to avoid potential hazards that could result in personal injury or damage to the device. Safety instructions are classified as follows in accordance with the seriousness of the risk.

Class	Degree of Risk
WARNING	Hazard that could result in serious injury or damage to the device if the safety instructions are not correctly followed.
CAUTION	Hazard that could result in light or moderate injury or damage to the device if the safety instructions are not correctly followed.
NOTICE	General product specification information highlighted to avoid product malfunction and performance reduction.

01

Disclaimer

The Jindell Company will not be responsible for accidents, equipment damage, or bodily injury resulting from:

1. repairs made by personal not authorized by the Jindell Company
 2. any changes, modifications, or alterations of its products
 3. the use of products or equipment made by the other manufacturers, except for those procures by the Jindell Company
 4. maintenance or repairs using parts or components other than those specified by the Jindell Company and other than in the original condition
 5. 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
 6. workplace conditions and environment or installation conditions which do not conform to those stated in this manual such as improper electrical power supply
 7. 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.

02

Caution

- The handpiece is supplied by Non-sterile condition before shipping. It must be autoclaved or sterilized before first use and after each use.
 - Immediately after a treatment, the handpiece should be cleaned, lubricated and sterilized. Failure to properly maintain the handpiece may lead to overheating, causing burn injuries or product failure.
 - If blood infiltrates inside a handpiece, an automatic handpiece cleaning and lubrication system may not totally clean the internal handpiece components and may lead to blood coagulation inside the handpiece. Coagulated blood may cause handpiece failure and overheating, causing burn injuries.
 - Never press the Push-Button Back Cap while the handpiece is in rotating. Otherwise it may result in overheating and burn injuries or product failure. Avoid the push button to contact with any oral tissue.
 - Supply coolant water and coolant air while using the handpiece. No supplying the coolant water and coolant air may result in overheating and burn injuries or product failure.
 - Proper cleaning& lubrication before sterilizations is essential to prevent the build-up of debris.
 - **Do not** use the handpiece for prophylaxis purposes. Polishing paste could enter the handpiece, causing the failure of the Push Button or may result in overheating and burn injuries or product failure all from the handpiece head.
 - Keep any debris away the handpiece or avoid any other foreign materials into the gear or the handpiece. Foreign materials remaining inside may result in overheating and burn injuries or product failure or other accidents.
 - Operators and all others in the area must wear eye protection and a mask when operating this handpiece.
- Do not** attempt to disassemble the handpiece nor tamper with the mechanism.

03

Caution

- **Do not** use bur/ drill with problems listed below as the bur may break, seize up (onger than 26mm) or disengage from the chuck.
 - Bent, deformed, worn, rusted, broken, deficient bur/ drill.
 - Bur/ drill which is cracked on the edge or axis.
 - Non-ISO (EN ISO) standard, or tampered bur/ drill
- Always keep the bur/ drill shank clean. Debris in the chuck could cause poor bur concentricity or low chuck retention force.
- **Do not** use the following fluids to wipe, immerse or clean the product; strong/super acid water, strong acid/alkaline chemicals, chlorine- containing solutions, solvents such as benzine or thinner.
- The operation of the handpiece is permitted only on dental units which correspond to the standards IEC 60601-1 (EN 60601-1) and IEC 60601-1-2 (EN 60601-1-2).
- Use a short shank FG bur/ drill for the product because the handpiece has the miniature head. Using a long bur/ drill with this handpiece may lead to premature abrasion of the bearings. In addition, sudden release, bend or breakage of the bur/ drill may occur.
- **Do not** use a surgical bur/ drill with its maximum length of 26mm or longer. Using such bur with this handpiece may lead to premature abrasion of the bearings. In addition, sudden release, bend or breakage of the bur/ drill may occur.
- Ball bearings in time, will become worn and will require replacement. Be sure to inspect the handpiece before use. If abnormal vibration or noise are found, the bearings or other internal parts may require replacement. Damaged parts may result in overheating and burn injuries or product failure. If overheating is suspected, stop using the handpiece immediately and contact your Authorized Dealer.
- Avoid crashing the handpiece. Take care not to drop the handpiece as it may cause serious damage and void the warranty. Be carefully!
- **Do not** use Dry-Heat sterilization; it will result in malfunctions and lead to premature bearing wear.

04

Caution

- **Rx only** 3. Federal law restricts this device to sale by or on the order of a licensed physician.
- Remove the bur (rotary instrument) only after the handpiece has completely stopped rotating.
- **Do not** use wire brush to clean the handpiece sheath. Wipe clean with alcohol-immersed cloth or cotton swab.
- **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.
- If damage due to wear happened, like as irregular running noise, significant vibration, Head overheating, unbalanced or with insufficient, please stop work immediately. Contact your authorized Jindell Dealer for service.

05

Connecting and Disconnecting the Handpiece from the Motor

Connecting

- Insert the handpiece direct into the motor (Fig. 1). When connecting an optic handpiece, turn the handpiece until it clicks and locks into position.
- Confirm that the handpiece is securely connected to the motor.

Disconnecting

- Hold the motor and the handpiece, then pull apart.

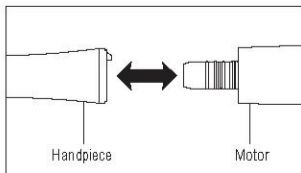


Fig. 1

Caution

- **Do not** connect or disconnect the handpiece until the motor has completely stopped.
- Connect ONLY to E type motors (ISO 3964 (EN ISO 3964)).
- **Do not** exceed the Max. of rotating speed (Motor) shown in Specifications.
- For Fiber Optic 20:1 gear ratio type: This handpiece is intended for use only with Surgical Units with Torque Calibration System. Using this product with other surgical units may damage the handpiece or bone.
- For Non- Fiber Optic 20:1 gear ratio type: The handpiece is designed for connection to a Non-optic motor or to a motor with a stopper pin. Connection to any other type of motor cannot lock the handpiece.

06

To Change the Bur (rotary instrument):

- ◆ Inserting the Bur
 - For CA Bur (Model: E11-CA/ E11L-CA/ E20/ E20L)
 - Insert the bur/ drill until it is correctly secured in place. (Fig. 2)
 - Depress the Push Button and insert the bur/drill into the chuck until the bur/ drill "notch" mechanism engages. Release the button.
 - Confirm that the bur/ drill is secure by gently pulling and pushing the bur/ drill without depressing the Push Button.

Caution

- Only LUX E20L/ LUX E20 type can use drill.

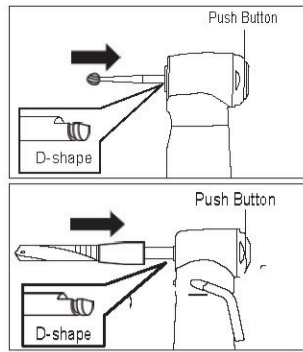


Fig. 2

- For FG Bur (Model: E11-FG/ E11L-FG/ E15/ E15L)
 - Insert the bur/ drill into the chuck.
 - Depress the Push Button to open the chuck (①).
 - Insert the bur/ drill fully into the chuck until it stops (②) then release the Push Button
 - Confirm that the bur/ drill is secure by gently pulling and pushing the bur/ drill without depressing the Push Button

Caution

- For easy operation of the Chuck Release Button, simply grip the handpiece and use your thumb tip to press the Chuck Release Button.

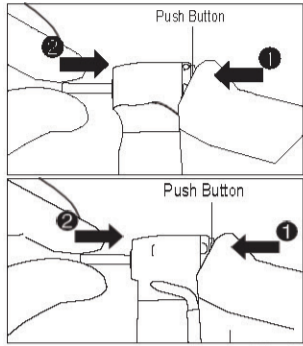


Fig. 3

Removing the Bur

- Depress the push button back cap to open the chuck (①) and, while the chuck is open, remove the bur/ drill (②).

Caution

- Always keep the bur/ drill shank clean. Debris in the chuck could cause poor bur concentricity or low chuck retention force.
- Always insert the bur/ drill all the way into the chuck. If insertion is insufficient, premature failure of the handpiece head bearings, or accidental release of the bur/ drill, may occur.
- Always follow the instructions provided by the bur/ drill manufacturer.
- **Do not** exceed the bur/ drill speed recommended by the bur/ drill manufacturer.
- **Do not** insert or remove the bur/ drill until rotation has completely stopped.
- **Do not** apply excess pressure to the bur/ drill as it may break or bend and become difficult to remove.
- After the bur/drill is locked in place, pull and push the bur/drill to make sure the bur/drill is locked. Depress the push button until it is almost parallel to the head cap.

If removing the bur/drill is difficult, grip the bur with fine pliers while depressing the Push-button, and gently remove the bur/ drill. This situation can be avoided by mounting and removing the bur/drill.

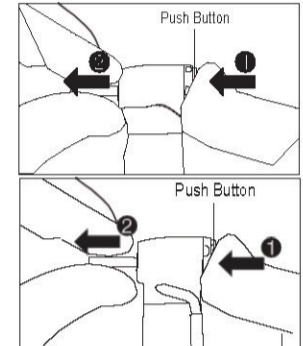


Fig. 4

Regarding the Spray Nozzle

Three irrigation methods are available for E20L / E20; External, Internal or both simultaneously, depending on the instrument and operation procedure.

External Spray Nozzle

- Connect the Irrigation Tube to the External Spray Nozzle firmly. (Fig. 5)

Internal Spray Nozzle

Only for a drill with internal irrigation system.

- Attach the Nozzle Holder. (Fig.6)
- Connect the Irrigation Tube to the Internal Spray Nozzle firmly. (Fig.7)
- Insert the end of the Internal Spray Nozzle into the hole at the top of the handpiece head, then attach the Internal Spray Nozzle into the slot on the Nozzle Holder. (Fig.8)

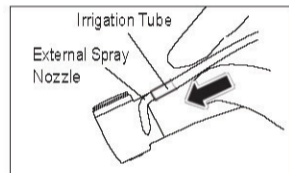


Fig. 5

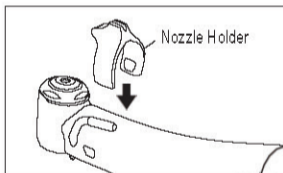


Fig. 6

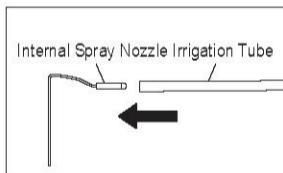


Fig. 7

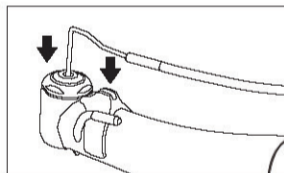


Fig. 8

Simultaneous External and Internal Irrigation

- Connect one end of the Y-Connector to the External Spray Nozzle and the other end into the Internal Spray Nozzle.
- Connect the Irrigation Tube to the Y-Connector firmly. (Fig.9)

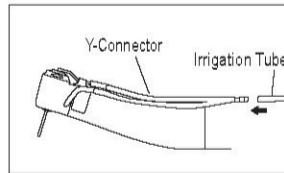


Fig. 9

Checking the Handpiece before Each Use

Follow the check procedure below before use. If any abnormalities are found, stop using the handpiece immediately and contact your Authorized Jindell Dealer.

- Check the Head Cap is firmly tightened.
- Check coolant water is flowing properly.
- Insert the bur/ drill. (Refer to " To Change the Bur (rotary instrument)")
- Rotate the handpiece for about one minute, using coolant water, and with the motor operating at full speed. During rotation, check for abnormalities such as abnormal rotation, vibration, noise.
- After the handpiece rotation has completely stopped, touch the handpiece head to confirm the head is NOT heating abnormally (Fig. 10).

Caution

- To avoid injury, keep your hands away from the bur during rotation.
- Immediately after a treatment, the handpiece should be cleaned, lubricated and sterilized. Failure to properly maintain the handpiece may lead to overheating, causing burn injuries or product failure.

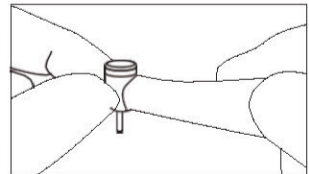


Fig. 10

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 eye protection, clothing, a mask and gloves to avoid infection & remove the handpiece from the motor,
- step 2: Remove the bur/ drill (rotary instrument),
- step 3: Only for E20L/ E20) Immerse about 20mm of the handpiece head in water, and rotate the handpiece for about 15 seconds while switching the Forward/Reverse rotation direction (Fig. 11),
- step 4: Disconnect the handpiece from the motor,
- Step 5: Manual Cleaning (External Surface). 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. **DO NOT** use a wire brush, lubrication,
- Final: Sterilization.

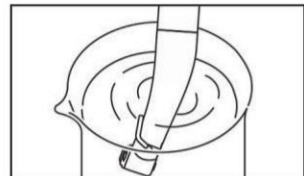


Fig. 11

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

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- Caution**  
- If water enters the handpiece, using an air syringe, blow air into the rear of the handpiece to remove the internal water.
 - **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.
 - Immediately after a treatment, the handpiece should be cleaned, lubricated and sterilized. Failure to properly maintain the handpiece may lead to overheating, causing burn injuries or product failure.
 - **Do not use** the following fluids to wipe, immerse or clean the product, strong/super acid water, strong acid/alkaline chemicals, chlorine- containing solutions, solvents such as benzene or thinner.
 - 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.

Cleaning of Optic Illumination Points

- Wipe it and clean the cellular optic glass rod exit hole which locates at the neck of turbine handpiece. Wipe it and clean with an alcohol immersed cotton swab (Fig.12) to remove all debris and oil to extend the effect of the light guide.
 - Do not Use a sharp tool to clean the cellular glass optic rod. It could damage the glass and reduce the light guide effect. But if you damage the cellular optic glass rod with sharp tools or at drop-down conditions, we will not carry the warranty risk.
- If illumination becomes dim please contact your Authorized Jindell Dealer

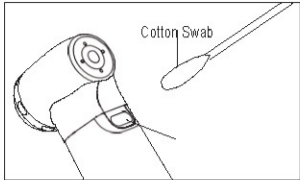


Fig. 12

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Caution  

- Proper cleaning & lubrication before sterilizations is essential to prevent the build-up of debris & remove the bur (rotary instrument). If blood remains on the internal surface it can become clotted and cause product failure.
- Do not autoclave the product with other instruments even when it is in a pouch. This is to prevent possible discoloration and damage to the product from chemical residue on other instruments.
- Never heat or cool the handpiece quickly; Rapid change in temperature could damage the glass rod or subject other metals to abnormal stress.
- To avoid product failure, do not use a sterilizer that exceeds a cycle temperature of 136°C, including the dry cycle. In some sterilizers, the chamber temperature may exceed 136°C. Contact the sterilizer manufacturer for detailed information about cycle temperatures.
- Keep the product in suitable atmospheric pressure, temperature, humidity, ventilation, and sunlight. The air should be free from dust, salt and Sulphur.
- Do not touch the product immediately after autoclaving as it will be very hot and must remain in a sterile condition.
- Autoclave sterilization is recommended for the product. The validity of other sterilization methods is not confirmed.
- Jindell recommended sterilization according to EN 13060.
- Make sure, that you only remove dry sterile goods. & Store sterile goods dust-free and dry.
- 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.
- Do not wash, soak, or wipe off the handpiece with a Potentially Corrosive Solution (strong acid, super acid solution) or cold sterilization solution.

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Cleaning (Spray Port)

- Insert the Irrigation Tube into the nozzle and rinse the inside with clean water.
- Internally clean the Internal Spray Nozzle and/ or the External Spray Nozzle by using Cleaning Wire. (Fig. 13,14) (E20L / E20)
- Connect the Irrigation Tube to each Spray Nozzle, and wash the inside with clean water. (Refer to "Regarding the Spray Nozzle") (E20L / E20)

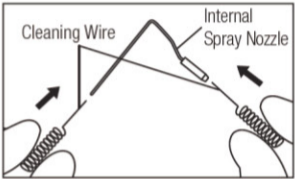


Fig. 13

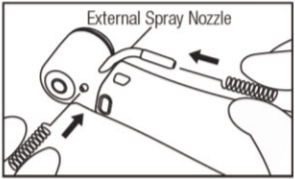



Fig. 14

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Caution 

- Do not forcibly insert the cleaning wire into the Spray Nozzle. Resultant port damage could cause the spray to be directed away from the bur/drill, and cause reduction of cooling efficiency.

Regular maintenance inspection

Every 3 months perform periodical maintenance checks, referring to the check sheet below. If any abnormalities are found, contact your Authorized Jindell Dealer.

Key Points to check	Details
Head Cap is loose	Check that the Head Cap must firmly tightened.
Rotation	Rotate the handpiece and check for abnormalities such as abnormal rotation, vibration, noise, and overheating situation.
Coolant Water	Operate the handpiece and check that the coolant water is flowing through all spray ports.


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Thermo washer Disinfectant

Handpiece with this symbol may be cleaned and disinfected with a thermal washer disinfectant.

To use a thermal washer disinfectant, first read the operation instructions for the unit. Strictly follow the instructions attached for cleaning mode of solution.

- Jindell recommends thermo washer disinfectants 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 disinfectant (complying with max. pH value of 10).
- Follow the instructions for use of the thermo washer disinfectant.

Caution 

- After washing with thermo-disinfectant, prior to lubrication, dry the product until all internal moisture is completely removed. Thermo-disinfectant moisture remaining inside the product could reduce the effect of lubrication and could cause corrosion inside of the product.
- 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 disinfectant or manually.
- Follow the disinfectant 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.

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Specifications

Model	E20L	E20	E16L	E16	E11L-CA	E11L-FG	E15L	E15
Max. Rotation Speed (Motor)	40,000 R.P.M.							
Max. Rotation Speed (Handpiece)	2,000 R.P.M.		2,500 R.P.M.		40,000 R.P.M.		200,000 R.P.M.	
Gear Ratio	20:1 Reduction		16:1 Reduction		1:1 Direct Drive		1:5 Increasing	
Bur Type	ISO 1797-1 (EN ISO 1797-1) Type1 Ø2.35mm Surgical Bur/Drill		ISO 1797-1 (EN ISO 1797-1) Type1 Ø2.35mm CA Bur			ISO 1797-1 (EN ISO 1797-1) Type3 Ø1.59-1.60mm Standard FG Bur		
Chuck Length	11.6 mm					11.9 mm	11.6 mm	
Max. Bur Length	22.5 mm					25mm (Recommended 19mm)		
Optic	Glass Rod	—	Glass Rod	—	Glass Rod	Glass Rod	Glass Rod	—
Water Spray type	External, Internal*		Single			Quattro		
Water Consumption	—		Min. 50mL/min (0.2MPa)					
Chip Air Consumption	—		Min. 1.5L/min (0.2MPa)					
Use Environment	Temperature: 10 - 40°C, Humidity: 30 - 75% (No Condensation)							
Transportation and Store Environment	Temperature -10 - 50°C, Humidity: 10 - 85%, Pressure: 500 - 1,060hPa							

* Only for a drill with internal irrigation system.

* Available models differ according to countries/regions.

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Disinfection: Manual disinfection - external

Jindell recommends the following products based on material compatibility. The microbiological efficacy must be ensured by the disinfectant manufacturer.

- Mikrozid AF made by Schülke & Mayr (liquid or cloths)
- WL-cid made by ALPRO
- Consumables required: Cloths for wiping off the medical device.
- Spray the disinfectant on a cloth, then thoroughly wipe down the medical device and leave the disinfectant to soak in according to the instructions from the disinfectant manufacturer.
- Follow the instructions for use of the disinfectant.
- FD 322 made by Dürr
- CaviCide made by Metrex

Disinfection: Manual disinfection - internal

The efficacy of manual internal disinfection must be demonstrated by the manufacturer of the disinfection agent. With Jindell products, use only compatibility of materials (e.g. WL-cid / made by ALPRO).

- Follow the instructions for use of the disinfectant.

Drying

- Manual Drying: Blow off the outside and inside with compressed air or 3 way syringe until water drops are no longer visible.
- Automatic Drying: The drying procedure is normally part of the cleaning program of the thermo washer disinfectant.

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Symbol



Refer to the chapter on Safety/ Warning symbol



Important information for users and service technicians



This product can be Thermo washer Disinfectable



This product can be steam- sterilized and Autoclvable at Max **134°C -1°C/+4°C (273°F -1.6°F/+7.4°F)**



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



Manufacturer **EC REP** Authorized representative in the European community.



Caution: U.S. Federal law restricts this device to sale by or on the order of a licensed physician.

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Lubrication:

Handpiece cleaning

- Make sure to **use the CORRECT application nozzle** (Fig.15) is connected to plastic valve at the top of the spray oil can. Firmly insert the application nozzle into the rear of the handpiece and activate the spray for 2- 3 seconds until the spray oil exhausts from the handpiece head.
- Always hold Spray Oil can upright. The spray lubricant is delivered from the can, into the handpiece, under pressure. To prevent the handpiece from slipping from the application nozzle, always hold the handpiece security to the application nozzle.

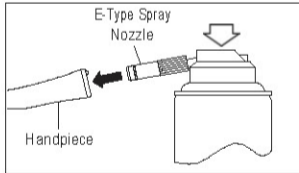


Fig. 15

Chuck cleaning

- Clean the Push Button chuck once a week.
- Mount the Tip Nozzle onto the spray can port.
- Lubricate the chuck directly where the bur is inserted (Fig. 16).
- Jindell **recommended lubricating the handpiece at least twice a day and lubricating the chuck (clamping) system weekly!**

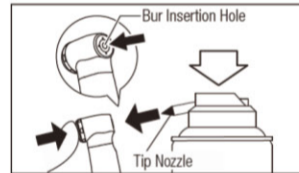


Fig. 16

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Spare Parts

Model	Compatible Product
Internal Spray Nozzle	E20L / E20
Nozzle Holder	
Y- Connector	
Cleaning Wire	
E-Type Spray Nozzle	All Contra Angle handpiece

Disposing product

In order to avoid the health risks of operators handling the disposal of medical equipment, as well as the risks of environmental contamination caused thereof, a surgeon or a dentist is required to confirm the equipment is sterile. Ask specialist firms who are licensed to dispose of specially controlled industrial wastes, to dispose the product for you.

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Caution 

- Hold the spray can upright.
- Firmly hold the handpiece to prevent it slipping when spray pressure is applied.
- Spray lubricant until it expels from the handpiece head.
- If the chuck is not regularly cleaned the chuck grip may be weakened and the bur may be accidentally released during use.
- If you wish to purge excessive oil from inside the handpiece, rotate the handpiece for approx. 15 seconds without a bur. During the rotation, do not depress the chuck release button, especially when using absorbent cloth to prevent oil from scattering. Depressing the push button during rotation may damage the chuck mechanism.
- If blood infiltrates inside a handpiece, an automatic handpiece cleaning and lubrication system may not totally clean the internal handpiece components and may lead to blood coagulation inside the handpiece. Coagulated blood may cause handpiece failure and overheating, causing burn injuries.

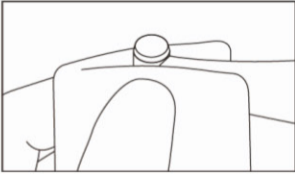


Fig. 17

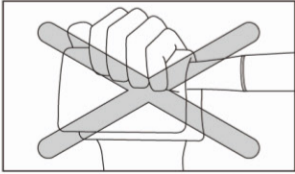


Fig. 18

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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 instructions. 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.

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Sterilization

Sterilize the product by autoclave sterilization. After each patient sterilize as noted below.

- Insert into an autoclave pouch and seal the pouch before Sterilization is recommended according to EN 868-5.
- Autoclavable under the conditions below.
Autoclave for more than 20min. at 121°C, or 15min. at 132°C, or 3min. at 134°C.
- The handpiece should remain in the autoclave pouch until required for use.
- Sterilization in a steam sterilizer (autoclave) in accordance with EN 13060 / ISO 17865-1
- Follow the steam sterilizer (autoclave) manufacturer's Instructions for Use.

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DECLARATION OF CE CONFORMITY

Manufactured/ Distributed by:



Jindell Medical Instruments Co., Ltd.
No. 367, Zhuliao Rd., Dashu Dist., 84043, Kaohsiung City, Taiwan (R.O.C.)
<http://www.taiwanitrade.com.tw/jindell>



Y. Sung Handelsvertretung
Dusselthaler Str.24, 40211, Dusseldorf, Germany

Declares under its own responsibility that following products:

Product Name: **Dental Contra Angle Handpiece**; Model in the Version: **Premium LUX 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 1797-1:2011; -ISO 9168:2009; -ISO 14457-1:2017; -ISO 7494-2; -ISO 14971:2012; -EN 15223-1:2012

※ Specifications maybe changed without notice.

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