

High-Speed Air Turbine Handpiece

OPERATION MANUAL

Please read this User Manual carefully before use, which will make your product last longer.

1. Product parts

Consists of handpiece head, handle, caudal thread, cartridge.

2. Intended use

High-speed turbine handpieces intended for removing carious material, excess filling material, cavity and crown preparation, finishing tooth preparations and restorations, root canal preparations and polishing teeth.

3. Technical parameters

- 1) Air pressure: 0.2- 0.3MPa
- 2) Bur diameter: ϕ 1.59-1.60mm (Applicable burs should be in compliance with Type 3 of ISO 1797-1)
- 3) Noise: \leq 70dB
- 4) Clamping force: \geq 22N
- 5) Water supply: \geq 50ml/min

⚠ WARNING: Do not exceed air pressure required in the technical parameters.

4. Connection and Disconnection of the handpiece

4-1 M4/B2 series

4-1-1 Connection

Insert the handpiece coupling correctly onto the hose connector and screw the hose nut. (Fig. 1)

i) Ensure the handpiece is connected firmly to the hose by pulling and pushing it gently.

4-2-2 Disconnection

Unscrew the hose nut and remove the handpiece from the hose.

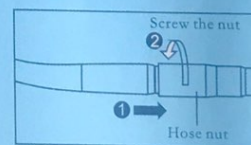


Fig. 1

4-2 QD Series

4-2-1 Connection

i) Insert the quick coupler onto the hose and screw the hose nut. (Fig.2)

ii) Pull the interface ring of quick coupling and insert the handpiece into it, then release the interfacing.

iii) Ensure the handpiece is connected firmly by pulling and pushing it gently.

4-2-2 Disconnection

Pull the interface ring of quick coupling and remove the handpiece.

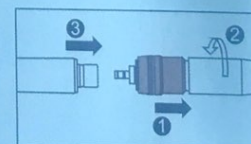


Fig. 2

⚠ CAUTION

Do not pull out the interface ring while supplying the air, or the handpiece will be forced out by the air pressure.

5. Mounting the Bur

5-1 To insert the bur

i) Depress the push button and insert the bur into bottom of the cartridge, then release the button. (Fig.3)

ii) Ensure that the bur is inserted securely by gently pulling and pushing the bur without depressing the push button.

5-2 To remove the bur depress the push button firmly and remove the bur.

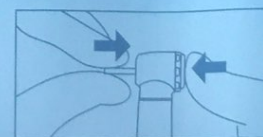


Fig. 3



CAUTION

- Do not use a handpiece when the bur is not mounted firmly.
- Do not use the handpiece until the handpiece has stopped rotating.
- Do not use the handpiece when the bur is damaged. Debris inside the chuck may cause vibration, weak chucking power or other abnormalities.
- Do not use the handpiece with a bur of type specified for its manual sector.
- Do not apply excessive pressure to the bur during use; this can lead to bur bending or breaking.
- Do not use burs that are bent, twisted, worn, cracked, deformed or have non-ISO standard conforming shanks; burs with these issues may cause poor break during use.

6. Test before use

Check the handpiece before each use. If any abnormalities are found such as loose parts, vibration, noise and overheat, stop using the device immediately and contact your authorized dealer.



WARNING

- Lubricate the handpiece in the morning and afternoon after working. If it is used continuously for more than 30 minutes, it must be lubricated with oil. Lubricate the handpiece before autoclaving.
- The device must be cleaned, lubricated and sterilized before each use. Before storing the device for a long time, lubricate the cartridge and shaft to avoid rusting.

7. Maintenance

Lubricant must be applied as follows after each use.

7-1 Head cleaning

Clean the handpiece head after each use.

- 1) Fill a cup halfway with clean water.
- 2) Remove dirt and debris from the holes. (Fig.4)
- 3) Activate the handpiece and immerse into water whilst bur is rotating. Start and stop rotating the bur for 2 to 3 seconds 3 times whilst the head remains in the water. (Fig. 5)
- 4) Stop the handpiece. Remove and wipe it dry with a clean soft cloth.
- 5) If there are dirt and debris on the handpiece head after above procedures, please clean it with a brush. (not a wire brush)

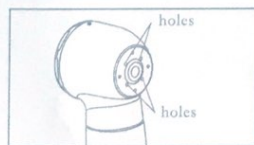


Fig.4



Fig.5

7-2 Handpiece cleaning

- 1) Remove dirt and debris from the product. Do not use a wire brush
- 2) Wipe it clean with alcohol-immersed cotton swab or cloth.



CAUTION

- After working with a thermocycling factor, first dry the handpiece thoroughly, remove the internal moisture and then apply lubricant to it.
- Moisture remaining in the handpiece will reduce the lubrication effect and cause internal corrosion.
- Do not use diluted acidic, high acid or alkali solution.

7-3 Lubrication

Lubricate the handpieces below after each use and before autoclaving.

M4/B2 series

- 1) Remove the handpiece from the hose. Remove the bur from the handpiece.
- 2) Mount the tip nozzle into the lubricant can. (Fig.6)
- 3) Insert the tip nozzle into the drive air port of the handpiece. Hold the handpiece and spray for approximately 2-3 seconds. Apply lubricant until it expels from the handpiece head. (Fig.7)

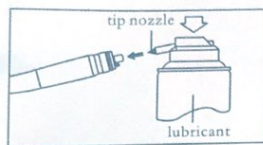


Fig.6

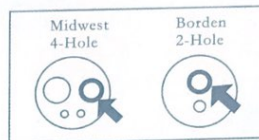


Fig.7

QD series

- 1) Remove the handpiece from the hose. Remove the bur from the handpiece.
 - 2) Insert the spray nozzle into the spray port nozzle on the lubricant can.
 - 3) Insert the spray nozzle in the rear of the handpiece.
- Hold the handpiece and spray for approximately 2-3 seconds. Apply lubricant until it expels from the handpiece head. (Fig.8)

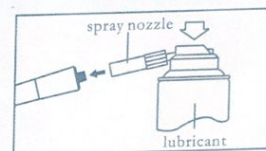


Fig.8

CAUTION

- When applying lubricant, be sure to hold the handpiece firmly to prevent the handpiece from slipping out of the hand due to the spray pressure.
- Hold the lubricant can upright.

Chuck cleaning

- 1) Mount the tip nozzle into the lubricant can.
- 2) Depress the push button and lubricate the chuck directly through the bur insertion hole. (Fig.9)

CAUTION

If the chuck is not regularly cleaned, the chuck grip may be weakened and the bur may be accidentally released while in operation.

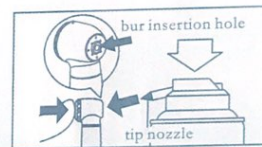


Fig.9

8 Sterilization

Reprocessing procedures have only limited implications to this dental instrument. The limitation of the numbers of reprocessing procedures is therefore determined by the function / wear of the device. In case of damage the device should be reprocessed before sending back to the manufacturer for repair.

8-1 Preparation at the Point of Use:

Disconnect the handpiece from the tube. Remove gross soiling of the instrument with cold water (<40°C) immediately after use. Don't use a fixating detergent or hot water (>40°C) as this can cause the fixation of residuals which may influence the result of the reprocessing process.

Store the instruments in a humid surrounding.

8-2 Transportation:

Safe storage and transportation to the reprocessing area to avoid any damage and contamination to the environment.

8-3 Preparation for Decontamination:

The devices must be reprocessed in a disassembled state.

8-4 Pre-Cleaning:

Do a manual pre-cleaning, until the instruments are visually clean. Submerge the instruments in a cleaning solution and flush the lumens with a water jet pistol with cold tap water for at least 10 seconds.

Clean the surfaces with a soft bristle brush.

8-5 Cleaning:

Regarding cleaning/ disinfection, rinsing and drying, it is to distinguish between manual and automated reprocessing methods.

Preference is to be given to automated reprocessing methods, especially due to the better standardizing potential and industrial safety

Manual Cleaning:

- 1) Wipe off and rinse the device with cold tap water until large debris/blood is removed.
- 2) Put the device in a suitable cleaning basin filled with a mild alkaline cleaner at 40-45°C. The instrument is brushed with a soft, nylon bristled brush for at least 30 seconds until all visible residues are removed. Pay special attention to the inside and the instrument tip.
- 3) Flush each inner lumen of the device with the cleaning solution 3 times by using cleaning adapter and 50ml syringe.
- 4) Remove the device from the cleaning basin.
- 5) Thoroughly rinse and flush the device and its inner lumen with de-ionized water. Repeat this step with fresh de-ionized water.
- 6) Dry the device with compressed air.

Automated Cleaning:

Use a washer-disinfector meeting the requirements of the ISO 15883 series.

Put the instruments into the machine on a tray and start the program

- 1) 4 min pre-washing with cold water (<40°C)
- 2) emptying
- 3) 5 min washing with a mild alkaline cleaner at 55°C
- 4) emptying
- 5) 3 min neutralising with warm water (>40°C);
- 6) emptying
- 7) 5 min intermediate rinsing with warm water (>40°C)
- 8) Emptying

The manual and automated cleaning processes have been validated by using 0.5% neodisher MediClean forte (Dr. Weigert).

8-6 Disinfection:

Automated 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 93°C has been validated for the device to achieve an A0 value of 3000.

After manual cleaning, the instrument should be sterilized immediately. A manual disinfection is not recommended.

8-7 Drying:

Automated Drying:

Drying of outside of instrument through drying cycle of washer/disinfector.

If needed, additional manual drying can be performed through lint free towel.

Insufflate cavities of instruments by using sterile compressed air.

8-8 Functional Testing, Maintenance:

Visual inspection for cleanliness of the instruments and reassembling. Functional testing according to instructions of use. If necessary, perform reprocessing process again until instrument is visibly clean.

Before packaging and autoclaving, make sure that the handpiece has been lubricated.

8-9 Packaging:

Pack the instruments in an appropriate packaging material for sterilization. The packaging material and system refer to EN ISO 11607.

8-10 Sterilization:

Sterilization of instruments 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.

Minimum requirements: 3 min at 134°C

Maximum sterilization temperature: 137°C

Flash sterilization is not allowed on lumen instruments!

8-11 Storage:

Storage of sterilized instruments in a dry, clean and dust free environment at modest temperatures, refer to label and instructions for use.

9. Replacing the cartridge

- 1) Locate the correct wrench tool on to the rear cap, then turn the wrench counter clockwise to loosen the cap. Remove the cap.
- 2) Use the bur to gently lever the entire cartridge out from the head.
- 3) Clean the head interior with spray lubricant.
- 4) Wipe the spray lubricant from the interior of the head.
- 5) Insert the new cartridge into the head by aligning the pin on the cartridge with the slot on the head. (Fig. 10)

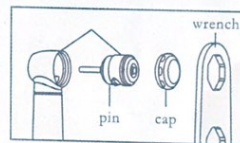


Fig. 10

10. Replacing the O-rings

Replace the O-rings if water is present in the exhaust air line. This is an indication of possible water leakage within the coupling.

Always change the complete set of O-rings.

- 1) Remove O-rings by hand. (Fig. 11)
- 2) Insert the complete set of new O-rings in the correct grooves.

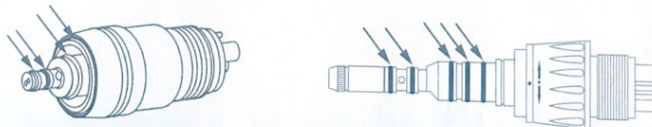


Fig. 11



CAUTION

- Do not force the new replacement O-ring with excessive pressure.
- When inserting new O-rings, make sure they are inserted in the correct grooves.

11. Environmental Conditions

Keep away from environmental conditions including but not limited with harmful chemicals like acids and alkali.

Use Conditions: Temperature: 5~40°C, Humidity: 10~80%RH, Atmospheric Pressure: 50~106 KPa

Storage Conditions: Temperature: -25~70°C, Humidity: 10~90%RH,

Atmospheric Pressure: 50~106 KPa



12. Troubleshooting

Malfunction	Cause	Solution
Unusual noise, reduced cutting power or failure to rotate	Debris in handpiece; cartridge damaged	Clean and lubricate the head; replace the cartridge
The water spray outlets do not spray mist	Water spray outlets isplugged	Clean the water spray outlets

Handpiece leaks water	O-rings damage	Replace the damaged component
Reduction in speed	Air pressure too low	Check and correct working air pressure
Handpiece will not engage bur or hold bur in chuck	Non-standard burs or damaged chuck	Replace burs or chuck
Abnormal bur rotation or failure to cut	O-rings or cartridge damage	Replace damaged components

13. Precautions for handling and operation

Please read these precautions carefully before use. The device is only to be used for its specified intended use. Safety instructions are intended to avoid potential hazards that could result in personal injury or damage to the device and are classified as below in accordance with the level of potential risk.

Class	Degree of Risk
 WARNING	Hazards that may result in serious injury/device damage if instructions are not correctly followed
 CAUTION	Hazards that may result in mild or moderate injury/device damage if instructions are not correctly followed






CAUTION







- All precautions should be read and understood before use.
- Handpiece operation should be in compliance with all precautions and instructions.
- This handpiece can only be used for dental treatment.
- This handpiece can only be used by professional dentists.
- Check the handpiece before each use. If any abnormalities are found such as loose parts, vibration, noise and overheat, stop using the device immediately and contact your authorized dealer.
- Damaged cartridge will generate much noise, and long-term use will affect the hearing. Please replace it as soon as possible. Burs used should be in compliance with the requirements of ISO 1797-1.
- Air/water pressure and flow should follow this instruction. Excess pressure will result in high speed rotation and damage shaft. Insert and remove burs until handpiece stops.
- Handpiece is supplied in a non-sterile state and must be autoclaved before use.
- The maximum time for using the device is 2 hours per day (24h).







WARNING

- Under normal operating conditions, air is exhausted from the back of the head of this handpiece. If air is directed into an open soft tissue wound or beneath the mucosa or dermis, injury to the patient could result from air emphysema or air embolism.
- Do not activate the press button of the handpiece during operation or slowing down. This leads to detachment of the rotary instrument and overheating of the press button.
- Do not replace any component without permission that could result in unforeseeable hazard. Please contact us for service if the handpiece or any other components are damaged. We will provide circuit diagrams, component part lists, descriptions, calibration instructions to assist to service personnel in parts repair.
- Supply coolant water and coolant air while using the handpiece. No supplying the coolant water and air may lead to overheating, causing burn injuries or function failure.

14. Symbol

No.	Symbols	Description
1		Consult instructions for use
2		DATE OF MANUFACTURE. This symbol shall be accompanied by a date to indicate the date of manufacture.
3		Symbol for "MANUFACTURER". This symbol shall be accompanied by the name and the address of the manufacturer.
4		CE Mark.
5		Symbol for "AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY". This symbol shall be accompanied by the name and the address of the authorized representative in the European Community, adjacent to the symbol.

No.	Symbols	Description
6		Sterilizable up to 134°C
7		Warning
8		For prescription use only
9		Non-sterile
10		This device can be washed via thermos disinfectant
11		For water adjustment. The water flow is the largest on the coincided position and no water flow in the 180 degrees position, both side is the same. After adjusting 180 degrees, there is no water.

No.	Symbols	Description
12		Storage Atmospheric Pressure: 50~106 KPa
13		Storage humidity: 10%~90%RH
14		Storage temperature: -25~70°C
15		Keep dry
16		This way up
17		Fragile

15. Service life

5 years (can withstand 250 reprocessing cycles)

16. Disposal of Product

In order to avoid the health risks to operators handling the disposal of medical equipment, and the risks of environmental contamination caused by the waste, a surgeon or a dentist is required to confirm the equipment is sterile. Entrust firms which are licensed to disposal of specially controlled industrial wastes to dispose the product for you. If you do not understand, please contact dealers or us.

17. EMC Requirement

This device complies with Medical EMC Standard IEC 60601-1-2:2014.

Guidance and manufacturer's declaration – electromagnetic emissions

The High Speed Air Turbine Handpieces is intended for use in the electromagnetic environment specified below.
The customer or the user of the High Speed Air Turbine Handpieces should assure that it is used in such an environment.

Emissions	Compliance	Electromagnetic environment-- guidance
RF emissions CISPR 11	Group 1	The High Speed Air Turbine Handpieces uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not Applicable	The High Speed Air Turbine Handpieces is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Guidance and manufacturer's declaration – electromagnetic immunity

The High Speed Air Turbine Handpieces is intended for use in the electromagnetic environment specified below.
The customer or the user of the High Speed Air Turbine Handpieces should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment--guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	Not Applicable	Mains power quality should be that of a typical commercial or hospital environment or typical home environment
Surge IEC 61000-4-5	± 1 kV line(s) and neutral	Not Applicable	Mains power quality should be that of a typical commercial or hospital environment or typical home environment
Voltage dips, short	<5 % UT (>95 % dip in UT)	Not Applicable	Mains power quality should be that of a typical commercial or

Interruptions and voltage variations on power supply input lines IEC 61000-4-11	for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5s		Hospital environment or typical home environment. If the user of the High Speed Air Turbine Handpieces requires continued operation during power mains interruptions, it is recommended that the High Speed Air Turbine Handpieces be powered from an uninterruptible power supply or a battery.
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Power frequency magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment or typical home environment.
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NOTE UT is the a.c. mains voltage prior to application of the test level

Guidance and manufacturer's declaration – electromagnetic immunity

The High Speed Air Turbine Handpieces is intended for use in the electromagnetic environment specified below.
The customer or the user of the High Speed Air Turbine Handpieces should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80MHz	Not Applicable	Portable and mobile RF communications equipment should be used no closer to any part of the High Speed Air Turbine Handpieces, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.6GHz	10 V/m 80 MHz to 2.6GHz	
			$d = 1,2\sqrt{P}$
			$d = 1,2\sqrt{P}$ 80MHz to 800 MHz
			$d = 2,3\sqrt{P}$ 800 MHz to 2,6 GHz
			Where P is the maximum output power

rating of the transmitter in watts (W)
according to the transmitter manufacturer
and d is the recommended separation
Distance in meters (m).

Field strengths from fixed RF transmitters,
as determined by an electromagnetic site
survey, should be less than the compliance
level in each frequency range.

Interference may occur in the vicinity of
Equipment marked with the following
symbol:



NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the High Speed Air Turbine Handpieces is used exceeds the applicable RF compliance level above, the High Speed Air Turbine Handpieces should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the High Speed Air Turbine Handpieces.

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the MODEL ST261

The High Speed Air Turbine Handpieces is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the High Speed Air Turbine Handpieces can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the High Speed Turbine Handpieces as recommended below, according to the maximum output power of the communications equipment.

Rated maximum	Separation distance according to frequency of transmitter (m)		
output power of transmitter (W)	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3

10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a. MEDICAL ELECTRICAL EQUIPMENT needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the ACCOMPANYING DOCUMENTS.

b. Portable and mobile RF communications equipment can affect MEDICAL ELECTRICAL EQUIPMENT.