CE 0197

AP-1
Instruction Manual

1 Product introduction

1.1 Preface

Guilin Woodpecker Medical Instrument Co., Ltd is a high-tech enterprise researching, developing, and producing dental products. Woodpecker owns a sound quality control system. Our main products include Ultrasonic Scaler, Curing Light, Ultrasonic Painless Periodontal Treatment Device, Dental Scaler and Air Polisher,etc.

1.2 Production introduction

AP-1 handpiece is a component of Dental Scaler and Air Polisher, consisting of a spray-head and a handle. The product bears the air polishing function of Dental Scaler and Air Polisher. It has isolated airway and waterway, and a disposable accessory nozzle will be installed on the top of the device when working, so that the air and water withpowder particles can be simultaneously ejected from the nozzle at the top of the handpiece. This product is used to remove the subgingival and supragingival biofilm and pigment, and maintain the implant to achieve the expected purpose.

1.3 Model and specifications

1.3.1 Model: AP-1

1.3.2 Specifications:

Length 101mm

Diameter φ16mm

Weight 35.2g

1.4 Structure and components

It is composed of spray-head and casing, etc.

1.5 Scope of application

It is suitable for the scope of application of PT-A Dental Scaler and Air Polisher.

1.6 Contraindications

Please refer to the instruction manual of PT-A Dental Scaler and Air Polisher.

1.7 Operation environment

1.7.1 Environment temperature:+5℃ ~ +40℃

1.7.2 Relative humidity: 30% ~ 75%

1.7.3 Atmospheric pressure: 70kPa ~ 106kPa

2 Product installation

2.1 Open the package, please check whether the product is complete and contact the supplier if necessary.

2.2 Install the handpiece after the installation of nozzle. Before installing the handpiece, use an air gun to dry the the connection end and the tail plug of the handpiece.

2.3 Ensure that the handpiece and the tail cord are well connected (as shown in Figure 1).

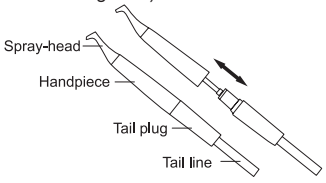

Figure 1

3 Product function and operation

3.1 Scaling

3.1.1 Check the handpiece before use to ensure that the water in the pipe inside is blown dry, and connect the handpiece while keeping the pipe dry.

3.1.2 The handpiece should be correctly installed on a suitable handpiece tail plug of Dental Scaler and Air Polisher, and adjusted to the appropriate water volume and air pressure through the main unit.

3.1.3 Generally, the handpiece is held in a pen-holding position.

3.1.4 When using the subgingival handpiece for normal subgingival air polishing, it is recommended to use a nozzle to remove the bioflm in the periodontal pocket at subgingival 4-9mm , and perform up and down motion for scaling.

3.1.5 When using the sandblasting handle for normal tooth cleaning, it is recommended that the distance between the nozzle outlet and the tooth surface should be 3-5mm, and the sandblasting direction should be 30-60 ° to the tooth surface, as shown in Fig. 2.

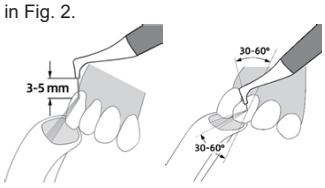

Figure 2

3.1.6 Please ensure that the handpiece has a normal waterway before use. Adjust the water volume and air pressure of the main unit to an appropriate level according to the conditions of biofilm or pigment when scaling. Do not spend too much time in local air polishing when scaling.

3.1.7 After the operation is completed, press the cleaning button, and ventilate for about 20 seconds under anhydrous conditions to flush the handpiece and tail pipe to prevent clogging. After cleaning, remove the handpiece for cleaning and disinfection.

3.2 Instructions for main components

3.2.1 Spray-head: it can be pulled out by rotation. In case of blockage, the user can rotate the spray-head to loosen and pull out it, and then use the needle to dredge. It can be sterilized at high temperature, as shown in Figure 3.

3.2.2 Handpiece: the main work unit, can be Can be steam sterilized.

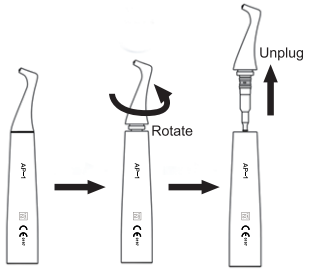

Figure 3

4 Other notes

4.1 It is forbidden to pull out the tail plug when the handpiece is working.

4.2 After use, please pull out the handpiece, clean and dry it for high temperature sterilization.

4.3 Our company is a professional manufacturer of medical devices. The maintenance, repair and modification of the product must be carried out by our company or our authorized distributors. We are responsible for the safety of maintenance, repair and modification only when they are replaced by the original accessories of our company and operated according to the instruction manual.

5 Troubleshooting

Fault	Possible cause	Solution
No air coming out of the handpiece	The air source or powder tank was not correctly installed.	Check the installation of air source or powder tank
	Clogged spray-head	Dredge the spray-head with a needle, then dry it with an air gun, or soak it in warm water and dry it
	Failure of main unit	Contact the local distributor or our company
No water coming out of the handpiece	The waterway was not correctly installed	Check whether a water bottle is installed or external water is connected
	The water supply mode was not correctly selected	Check the water supply mode of main unit
	Clogged waterway of the handpiece	Blow the handpiece waterway with an air gun
	Failure of main unit	Contact the local distributor or our company
Water leakage at the connecting end between the spray-head and the handpiece	Damaged waterproof O-ring	Replace waterproof O-ring
Water leakage at the connecting end between the handpiece and the tail plug	Damaged waterproof O-ring	Replace waterproof O-ring

6.Cleaning, Disinfection and Sterilization

Warnings

The use of ultrasound cleaning device and strong cleaning and disinfection fluids (alkaline pH>9 or acid pH <5) can reduce the life span of products. The manufacturer takes no responsibility in such cases.

This device shall not be exposed to high temperature above 138℃.

Processing limit

The products have been designed for a large number of sterilization cycles. The materials used in manufacture were selected accordingly. However with every renewed preparation for use, thermal and chemical stresses will result in ageing of the products. The allowed maximum times of sterilization for handpiece is 1000 times.

6.1 Initial processing

6.1.1 Processing principles

It is only possible to carry out effective sterilization after the completion of effective cleaning and disinfection. Please ensure that, as part of your responsibility for the sterility of products during use, only sufficiently validated equipment and product-specific procedures are used for cleaning/disinfection and sterilization, and that the validated parameters are adhered to during every cycle.

Please also observe the applicable legal requirements in your country as well as the hygiene regulations of the hospital or clinic, especially with regard to the additional requirements for the inactivation of prions.

6.1.2 Post-operative treatment

The post-operative treatment must be carried out immediately, no later than 30 minutes after the completion of the operation. The steps are as follows:

1. Let the Dental Scaler And Air Polisher works for 20-30 seconds at maximum water volume to flush the handpiece;

2. Remove the handpiece from the Dental Scaler And Air Polisher, and rinse away the dirt on the surface of handpiece with cool water;

3. Dry the handpiece with a clean, soft cloth and place it in a clean tray.

6.2 Preparation before cleaning

Steps

Tools: tray, soft brush, clean and dry soft cloth

1. Unscrew the sprinkler head from handpiece unterclockwise and put it into the tray.

2. Use a clean soft brush to carefully brush the joints between handpiece and the connector of the sprinkler head and the handpiece until the dirt on surface is not visible. Then use soft cloth to dry the handpiece and accessories and put them into a clean tray.

Disassembling steps, Figure 4

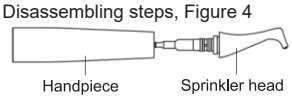

Figure 4

6.3 Cleaning

The cleaning should be performed no later than 24 hours after the operation.

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.

Automated cleaning

• The cleaner is proved to be valid by CE certification in accordance with EN ISO 15883.

• There should be a flushing connector connected to the inner cavity of the product.

• The cleaning procedure is suitable for the handpiece, the flushing period is sufficient, and ultrasonic cleaning is prohibited.

It is recommended to use a washer-disinfector in accordance with EN ISO 15883.

1.Carefully place the handpieces in the disinfection basket. Fixture of the handpiece is permissible only when they are freely removable in the unit. The handpieces are not permitted to contact with each other.

2.Use a suitable rinsing adaptor, and connect the internal water lines to the rinsing connection of the washer-disinfector.

3. start the program:

- 3 min pre-cleaning with cold tap water
- emptying
- 5 min washing with 0.5% neodisher MediZym in deionized water(<45℃)
- emptying
- 1 min intermediate rinsing with cold deionized water .
- emptying
- 1 min intermediate rinsing with cold deionized water .
- Emptying

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

6.4 Disinfection

Disinfection must be performed no later than 2 hours after the cleaning phase. Automated disinfection is preferred if conditions permit.

Automated disinfection-Washer-disinfector

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

•Use high temperature disinfection function. The temperature does not exceed 134 °C, and the disinfection under the temperature cannot exceed 20 minutes.

•The disinfection cycle is in accordance with the disinfection cycle in EN ISO 15883.

Cleaning and disinfecting steps by using Washer-disinfector

1. Carefully place the handpieces in the disinfection basket. Fixture of the handpiece is permissible only when they are freely removable in the unit. The handpieces are not permitted to contact with each other.

2. Use a suitable rinsing adaptor, and connect the internal water lines to the rinsing connection of the washer-disinfector.

3. Start the program.

4. After the program is finished, remove the handpieces from the washer-disinfector, inspect (refer to section "Inspection and Maintenance") and packaging (refer to chapter "Packaging"). Dry the handpiece repeatedly if necessary (refer to section "Drying").

* The intrinsic suitability of the handpiece for effective cleaning and disinfection using the above automated cleaning and disinfection procedures was verified by a certified facility.

Notes

a) Before use, you must carefully read the operating instructions provided by the equipment manufacturer to familiarize yourself with the disinfection process and precautions.

b) With this equipment, cleaning, disinfection and drying will be carried out together.

c) Cleaning: (c1) The cleaning procedure should be suitable for the product to be treated. The flushing period should be sufficient (5-10 minutes). Pre-wash for 3 minutes, wash for another 5 minutes, and rinse it for twice with each rinse lasting for 1 minute. (c2) In the washing stage, the water temperature should not exceed 45 °C, otherwise the protein will solidify and it is difficult to remove. (c3) The solution used is deionized water. (c4) During the use of cleaner, the concentration and time provided by manufacturer shall be obeyed. For the use of cleaner, please refer to the instruction manual of cleaner.

d) Disinfection: (d1) For the disinfection here, the temperature is 93 °C, the time is 5 min, and A0>3000.

e) Only deionized water with a small amount of microorganisms (<10 cfu/ml) can be used for all rinsing steps. (For example, deionized water that is in accordance with the European Pharmacopoeia or the United States Pharmacopoeia).

f) After cleaning and disinfection, the chemical residue should be in accordance with the cytotoxicity test.

g) The air used for drying must be filtered by HEPA.

h) Regularly repair and inspect the disinfector.

6.5 Drying

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 handpiece against the white paper (white cloth), and then dry the handpiece with filtered dry compressed air (maximum pressure 3 bar). Until no liquid is sprayed onto the white paper (white cloth), the handpiece drying is completed.

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

Notes

a) The drying of product must be performed in a clean place.

b) The drying temperature should not exceed 138 °C;

c) The equipment used should be inspected and maintained regularly.

6.6 Inspection and maintenance

In this chapter, we only check the appearance of the handle. After inspection, if there is no problem, the handpiece should be immediately reassembled, tighten the sprinkler head clockwise.

1. Check the handpiece. If there is still visible stain on the handpieceafter cleaning/disinfection, the entire cleaning/disinfection process must be repeated.

2. Check the handpiece. If it is obviously damaged, smashed, detached, corroded or bent, it must be scrapped and not allowed to continue to be used.

3. Check the handpiece. If the accessories are found to be damaged, please replace it before use. And the new accessories for replacement must be cleaned, disinfected and dried.

4. If the service time (number of times) of the handpiece reaches the specified service life (number of times), please replace it in time.

6.7 Packaging

The disinfected and dried handpieces and their accessories are assembled and quickly packaged in a medical sterilization bag (or special holder, sterile box).

Precautions

(1) The package used conforms to ISO 11607;

(2) It can withstand a temperature of 138°C and has sufficient steam permeability;

(3) The packaging environment and related tools must be cleaned regularly to ensure cleanliness and prevent the introduction of contaminants;

(4) Avoid contact with parts of different metals when packaging.

6.8 Sterilization

Use only the following steam sterilization procedures (fractional pre-vacuum procedure*) for sterilization, and other sterilization procedures are prohibited:

1. The steam sterilizer complies with EN13060 or is certified according to EN 285 to comply with EN ISO 17665;

2. The highest sterilization temperature is 138 °C;

3. The sterilization time is at least 5 minutes at a temperature of 134 °C.

4. Allow a maximum sterilization time of 20 minutes at 134 °C.

Precautions

(1) Only products that have been effectively cleaned and disinfected are allowed to be sterilized;

(2) Before using the sterilizer for sterilization, read the Instruction Manual provided by the equipment manufacturer and follow the instructions.

(3) Do not use hot air sterilization and radiation sterilization as this may result in damage to the product;

(4) 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.

7 Storage,and transportation

7.1 Storage

7.1.1 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;

7.1.2 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.

Precautions

(1) The storage environment should be clean and must be disinfected regularly;

(2) Product storage must be batched and marked and recorded.

7.2 Transportation

7.2.1 Prevent excessive shock and vibration during transportation, and handle with care;

7.2.2 It should not be mixed with dangerous goods during transportation.

7.2.3 Avoid exposure to sun or rain or snow during transportation.

8 Environment protection

The product does not contain any harmful ingredients. It can be processed or destroyed in accordance with the relevant local regulations.

9 After-sales service

Since the date of sale, if the equipment fails to work normally due to quality problems within one year, our company will be responsible for the maintenance free of charge with the warranty card. Refer to the warranty instructions in the warranty card for more details.

10 Symbol instruction


Follow instructions for use

Can be autoclaved


Used indoor only


Appliance complies with WEEE directive

Atmospheric pressure for storage

Temperature limit for storage

Humidity limit for storage

CE mark product

Authorised Representative in the EUROPEAN COMMUNITY

11 Statement

Make sure that the inside of the handpiece connection end and the connection end of tail plug are dry each time the handpiece is connected, so as to avoid the blockage of the spray-head caused by the moisture of the powder, as shown in Figure 5.

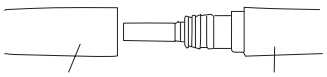

Figure 5

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CE 0197

AP-2 Subgingival Handpiece Instruction Manual

1 Product introduction

1.1 Preface

Guilin Woodpecker Medical Instrument Co., Ltd is a high-tech enterprise researching, developing, and producing dental products. Woodpecker owns a sound quality control system. It has two brands: Woodpecker and DTE. Our main products include Ultrasonic Scaler, Curing Light, Ultrasonic Painless Periodontal Treatment Device, Dental Scaler and Air Polisher,etc.

1.2 Production introduction

AP-2 subgingival handpiece is a component of Dental Scaler and Air Polisher, consisting of a spray-head and a handle. The product bears the air polishing function of Dental Scaler and Air Polisher. It has isolated airway and waterway, and a disposable accessory nozzle will be installed on the top of the device when working, so that the air and water withpowder particles can be simultaneously ejected from the nozzle at the top of the handpiece. This product is used to remove the subgingival and supragingival biofilm and pigment, and maintain the implant to achieve the expected purpose.

1.3 Model and specifications

1.3.1 Model: AP-2

1.3.2 Specifications:

Length 101mm

Diameter ф16mm

Weight 35.6g

1.4 Structure and components

It is composed of spray-head and casing, etc.

1.5 Scope of application

It is suitable for the scope of application of PT-A Dental Scaler and Air Polisher.

1.6 Contraindications

Please refer to the instruction manual of PT-A Dental Scaler and Air Polisher.

1.7 Operation environment

1.7.1 Environment temperature:+5℃ ~ +40℃

1.7.2 Relative humidity: 30% ~ 75%

1.7.3 Atmospheric pressure: 70kPa ~ 106kPa

2 Product installation

2.1 Open the package, please check whether the product is complete and contact the supplier if necessary.

2.2 Install an accessory nozzle before use. Screw in the nozzle to the top of the subgingival handpiece, and then tighten the nozzle with a wrench (as shown in Figure 1).

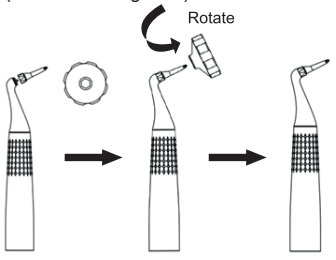

Figure 1

Install the handpiece after the installation of nozzle. Before installing the handpiece, use an air gun to dry the the connection end and the tail plug of the handpiece.

Ensure that the handpiece and the tail cord are well connected (as shown in Figure 2).

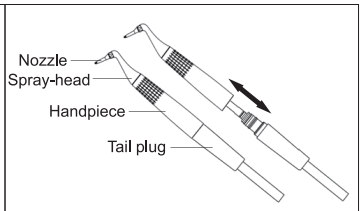

Figure 2

3 Product function and operation

3.1 Scaling

3.1.1 Check the handpiece before use to ensure that the water in the pipe inside is blown dry, and connect the handpiece while keeping the pipe dry.

3.1.2 The handpiece should be correctly installed on a suitable handpiece tail plug of Dental Scaler and Air Polisher, and adjusted to the appropriate water volume and air pressure through the main unit.

3.1.3 Check whether the nozzle is unobstructed before each use.

3.1.4 Generally, the handpiece is held in a pen-holding position.

3.1.5 When using the subgingival handpiece for normal subgingival air polishing, it is recommended to use a nozzle to remove the bioflm in the periodontal pocket at subgingival 4-9mm , and perform up and down motion for scaling.

3.1.6 The air polishing time of each periodontal pocket is recommended for no more than 5 seconds.

3.1.7 Please ensure that the handpiece has a normal waterway before use. Adjust the water volume and air pressure of the main unit to an appropriate level according to the conditions of biofilm or pigment when scaling. Do not spend too much time in local air polishing when scaling.

3.1.8 After the operation is completed, press the cleaning button, and ventilate for about 20 seconds under anhydrous conditions to flush the handpiece and tail pipe to prevent clogging. After cleaning, remove the handpiece for cleaning and disinfection.

3.2 Instructions for main components

3.2.1 Spray-head: it can be pulled out by rotation. In case of blockage, the user can rotate the spray-head to loosen and pull out it, and then use the needle to dredge. It can be sterilized at high temperature, as shown in Figure 3.

3.2.2 Handpiece: Working part, can be sterilized at high temperature.

3.2.3 Nozzle: Accessory.

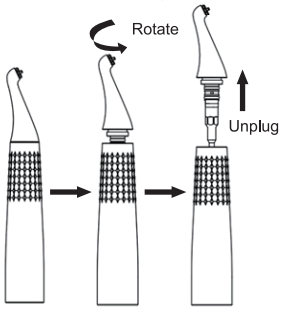

Figure 3

4 Other notes

4.1 It is forbidden to pull out the tail plug when the handpiece is working.

4.2 After use, please pull out the handpiece, clean and dry it for high temperature sterilization.

4.3 Our company is a professional manufacturer of medical devices. The maintenance, repair and modification of the product must be carried out by our company or our authorized distributors. We are responsible for the safety of maintenance, repair and modification only when they are replaced by the original accessories of our company and operated according to the instruction manual.

5 Troubleshooting

Fault	Possible cause	Solution
No air coming out of the handpiece	The air source or powder tank was not correctly installed.	Check the installation of air source or powder tank
	Clogged nozzle	Replace the disposable nozzle
	Clogged spray-head	Dredge the spray-head with a needle, then dry it with an air gun, or soak it in warm water and dry it
	Failure of main unit	Contact the local distributor or our company
No water coming out of the handpiece	The waterway was not correctly installed	Check whether a water bottle is installed or external water is connected
	The water supply mode was not correctly selected	Check the water supply mode of main unit
	Clogged nozzle	Replace the disposable nozzle
	Clogged waterway of the handpiece	Blow the handpiece waterway with an air gun
	Failure of main unit	Contact the local distributor or our company
Water leakage at the connecting end between the spray-head and the handpiece	Damaged waterproof O-ring	Replace waterproof O-ring
Water leakage at the connecting end between the handpiece and the tail plug	Damaged waterproof O-ring	Replace waterproof O-ring

6.Cleaning, Disinfection and Sterilization

Warnings

The use of ultrasound cleaning device and strong cleaning and disinfection fluids (alkaline pH>9 or acid pH <5) can reduce the life span of products. The manufacturer takes no responsibility in such cases.

This device shall not be exposed to high temperature above 138℃ .

Processing limit

The products have been designed for a large number of sterilization cycles. The materials used in manufacture were selected accordingly. However with every renewed preparation for use, thermal and chemical stresses will result in ageing of the products. The allowed maximum times of sterilization for handpiece is 1000 times.

6.1 Initial processing

6.1.1 Processing principles

It is only possible to carry out effective sterilization after the completion of effective cleaning and disinfection. Please ensure that, as part of your responsibility for the sterility of products during use, only sufficiently validated equipment and product-specific procedures are used for cleaning/disinfection and sterilization, and that the validated parameters are adhered to during every cycle.

Please also observe the applicable legal requirements in your country as well as the hygiene regulations of the hospital or clinic, especially with regard to the additional requirements for the inactivation of prions.

6.1.2 Post-operative treatment

The post-operative treatment must be carried out immediately, no later than 30 minutes after the completion of the operation. The steps are as follows:

1. Let the Dental Scaler And Air Polisher works for 20-30 seconds at maximum water volume to flush the handpiece;

2. Remove the handpiece from the Dental Scaler And Air Polisher, and rinse away the dirt on the surface of handpiece with pure water (or distilled water/deionized water);

3. Dry the handpiece with a clean, soft cloth and place it in a clean tray.

Notes:

a) The water used here must be pure water, distilled water or deionized water.

6.2 Preparation before cleaning

Steps

Tools: tray, soft brush, clean and dry soft cloth

1. Unscrew the sprinkler head from handpiece unterclockwise and put it into the tray.

2. Use a clean soft brush to carefully brush the joints between handpiece and the connector of the sprinkler head and the handpiece until the dirt on surface is not visible. Then use soft cloth to dry the handpiece and accessories and put them into a clean tray. The cleaning agent can be pure water, distilled water or deionized water.

Disassembling steps, Figure 4

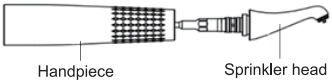

Figure 4

6.3 Cleaning

The cleaning should be performed no later than 24 hours after the operation.

The cleaning can be divided into automated cleaning and manual cleaning. Automated cleaning is preferred if conditions permit.

Automated cleaning

▪ The cleaner is proved to be valid by CE certification in accordance with EN ISO 15883.

▪ There should be a flushing connector connected to the inner cavity of the product.

▪ The cleaning procedure is suitable for the handpiece, the flushing period is sufficient, and ultrasonic cleaning is prohibited.

It is recommended to use a washer-disinfector in accordance with EN ISO 15883. For the specific procedure,

please refer to the automated disinfection section in the next section "Disinfection".

Notes

a) The cleaning agent used here must be compatible with the handpiece and only freshly prepared solutions can be used.

b) In washing stage, the water temperature should not exceed 45 °C, otherwise the protein will solidify and it would be difficult to remove.

c) After cleaning, the chemical residue should be in accordance with the cytotoxicity test.

6.4 Disinfection

Disinfection must be performed no later than 2 hours after the cleaning phase. Automated disinfection is preferred if conditions permit.

Automated disinfection-Washer-disinfector

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

•Use high temperature disinfection function. The temperature does not exceed 134 ° C, and the disinfection under the temperature cannot exceed 20 minutes.

•The disinfection cycle is in accordance with the disinfection cycle in EN ISO 15883.

Cleaning and disinfecting steps by using Washer-disinfector

1. Carefully place the handpieces in the disinfection basket. Fixture of the handpiece is permissible only when they are freely removable in the unit. The handpieces are not permitted to contact with each other.

2. Use a suitable rinsing adaptor, and connect the internal water lines to the rinsing connection of the washer-disinfector.

3. Start the program.

4. After the program is finished, remove the handpieces from the washer-disinfector, inspect (refer to section "Inspection and Maintenance") and packaging (refer to chapter "Packaging"). Dry the handpiece repeatedly if necessary (refer to section "Drying").

* The intrinsic suitability of the handpiece for effective cleaning and disinfection using the above automated cleaning and disinfection procedures was verified by a certified facility. (Use the G 7836 CD washer disinfector ,Miele & Cie. KG, Gutersloh,(thermal disinfection), and the cleaning agent neodisher MediZym (Dr. Weigert)).

Notes

a) Before use, you must carefully read the operating instructions provided by the equipment manufacturer to familiarize yourself with the disinfection process and precautions.

b) With this equipment, cleaning, disinfection and drying will be carried out together.

c) Cleaning: (c1) The cleaning procedure should be suitable for the product to be treated. The flushing period should be sufficient (5-10 minutes). Pre-wash for 3 minutes, wash for another 5 minutes, and rinse it for twice with each rinse lasting for 1 minute. (c2) In the washing stage, the water temperature should not exceed 45 °C, otherwise the protein will solidify and it is difficult to remove. (c3) The solution used is deionized water. (c4) During the use of cleaner, the concentration and time provided by manufacturer shall be obeyed. The used cleaner is 5% Neutral detergent (neodisher MediZym (Dr. Weigert)).

d) Disinfection: (d1) For the disinfection here, the temperature is 93 °C, the time is 5 min, and A0>3000.

e) Only deionized water with a small amount of microorganisms (<10 cfu/ml) can be used for all rinsing steps. (For example, deionized water that is in accordance with the European Pharmacopoeia or the United States Pharmacopoeia).

f) After cleaning and disinfection, the chemical residue should be in accordance with the cytotoxicity test.

g) The air used for drying must be filtered by HEPA.

h) Regularly repair and inspect the disinfector.

6.5 Drying

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 handpiece against the white paper (white cloth), and then dry the handpiece with filtered dry compressed air (maximum pressure 3 bar). Until no liquid is sprayed onto the white paper (white cloth), the handpiece 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.

Notes

a) The drying of product must be performed in a clean place.

b) The drying temperature should not exceed 138 °C;

c) The equipment used should be inspected and maintained regularly.

6.6 Inspection and maintenance

In this chapter, we only check the appearance of the handle. After inspection, if there is no problem, the handpiece should be immediately reassembled, tighten the sprinkler head clockwise.

1. Check the handpiece. If there is still visible stain on the handpieceafter cleaning/disinfection, the entire cleaning/disinfection process must be repeated.

2. Check the handpiece. If it is obviously damaged, smashed, detached, corroded or bent, it must be scrapped and not allowed to continue to be used.

3. Check the handpiece. If the accessories are found to be damaged, please replace it before use. And the new accessories for replacement must be cleaned, disinfected and dried.

4. If the service time (number of times) of the handpiece reaches the specified service life (number of times), please replace it in time.

6.7 Packaging

The disinfected and dried handpieces and their accessories are assembled and quickly packaged in a medical sterilization bag (or special holder, sterile box).

Precautions

(1) The package used conforms to ISO 11607;

(2) It can withstand high temperature of 138 °C and has sufficient steam permeability;

(3) The packaging environment and related tools must be cleaned regularly to ensure cleanliness and prevent the introduction of contaminants;

(4) Avoid contact with parts of different metals when packaging.

6.8 Sterilization

Use only the following steam sterilization procedures (fractional pre-vacuum procedure*) for sterilization, and other sterilization procedures are prohibited:

1. The steam sterilizer complies with EN13060 or is certified according to EN 285 to comply with EN ISO 17665;

2. The highest sterilization temperature is 138 °C;

3. The sterilization time is at least 5 minutes at a temperature of 134 °C.

4. Allow a maximum sterilization time of 20 minutes at 134 °C.

Verification of the fundamental suitability of the handpiece for effective steam sterilization was provided by a verified testing laboratory. (Used the Systec DX-150 Middle-sized hospital moist heat sterilizer, MMM GmbH, Eurofins Munich).

Precautions

(1) Only products that have been effectively cleaned and disinfected are allowed to be sterilized;

(2) Before using the sterilizer for sterilization, read the Instruction Manual provided by the equipment manufacturer and follow the instructions.

(3) Do not use hot air sterilization and radiation sterilization as this may result in damage to the product;

(4) 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.

7 Storage,and transportation

7.1 Storage

7.1.1 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;

7.1.2 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.

Precautions

(1) The storage environment should be clean and must be disinfected regularly;

(2) Product storage must be batched and marked and recorded.

7.2 Transportation

7.2.1 Prevent excessive shock and vibration during transportation, and handle with care;

7.2.2 It should not be mixed with dangerous goods during transportation.

7.2.3 Avoid exposure to sun or rain or snow during transportation.

8 Environment protection

The product does not contain any harmful ingredients. It can be processed or destroyed in accordance with the relevant local regulations.

9 After-sales service

Since the date of sale, if the equipment fails to work normally due to quality problems within one year, our company will be responsible for the maintenance free of charge with the warranty card. Refer to the warranty instructions in the warranty card for more details.

10 Symbol instruction

	Follow instructions for use
134℃	Can be autoclaved
	Used indoor only
	Appliance complies with WEEE directive
106kPa 70kPa	Atmospheric pressure for storage
+55℃ -20℃	Temperature limit for storage
93% 10%	Humidity limit for storage
CE 0197	CE mark product
EC REP	Authorised Representative in the EUROPEAN COMMUNITY

11 Statement

Make sure that the inside of the handpiece connection end and the connection end of tail plug are dry each time the handpiece is connected, so as to avoid the blockage of the spray-head caused by the moisture of the powder, as shown in Figure 5.

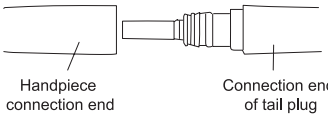

Figure 5

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