Dentalsalemall

www.dentalsalemall.com

CE 0123

MaxFill-G/P

Gutta-percha Obturation System Instruction Manual



Guilin Refine Medical Instrument Co., Ltd.

RF-HMF-M001 Version:1.7 20250306

MaxFill-G

Introduction

Thank you for purchase MaxFill-G Hot Melting and Filling Gun developed by Guilin Refine Medical Instrument Co., Ltd., a Hi-tech enterprise developing, manufacturing, and selling dental instruments. Refine has excellent Quality Control System. To guarantee correct and safe operation, please read this Instruction Manual carefully before use. Depending on the level of risk involved, safety requirements are classed under the following indications:

⚠ **Danger:** (always referred to personal injury).

⚠ **Warning:** (referred to possible damage to property)

1 Product introduction

1.1 Intended use

Heat up and soften gutta-percha, and fill the gutta-percha into the root canal.

1.2 Patient target groups:

Adults and Pediatrics.

1.3 Intended users:

The product is intended for use in hospitals and dental clinics only. The user must be professionally trained and qualified dentists.

1.4 Applied part:

Cone head, gutta-percha injection needle, heat insulation hood, heat insulation sleeve for injection needle.

1.5 Diagram of components and control buttons

The MaxFill-G is equipped with a display screen and a control button on both the left and right sides. And the design of left and right sides are perfectly symmetrical, which enables either left-hand or right-hand operation.

Figure 1-0 Matchine and components schematic

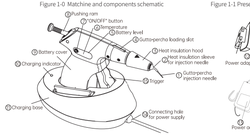


Figure 1-1 Preset temperature



1) "ON/OFF" button:

a) In the OFF state, long press the left or right "ON/OFF" button can turn on the power. After the power is turned on, the left and right displays will be lit at the same time.

b) In the ON state, long press the left or right "ON/OFF" button can turn off the power.

Note: If there is no operation for 10 minutes, the Hot Melting and Filling Gun will automatically shut down.

2) Temperature control button: (Note: The temperature control button and the "ON/OFF" button are the same button. After powers on, the button acts as temperature control button.)

Lightly press the button to change the preset temperature for heating the gutta-percha. The temperature will change in the sequence of 150℃ , 180℃ , 200℃ , 230℃ as shown in Figure 1, and back to 150° when you press the button in 230℃ .

Gutta-percha injection needle	Temperature
25G	180℃ -230℃
23G	180℃ -200℃
20G	180℃ -200℃

Table 1 Recommended temperature setting

3) Battery level:

The actual power of the battery is displayed in real time on the screen. When the battery is fully charged, the power of the OLED display is displayed as five grids. When the battery level is one grid, it indicates that the battery is low and needs to be charged in time. When the battery level is displayed as a space, it indicates that the battery is very low and needs to be charged immediately.

Note: During normal use, try not to let the battery level reduced to space status (completely no power) before charge, which will shorten the service life of battery.

⚠ **Warning:**

If the device has not been used for more than one month, the battery needs to be recharged. If the device is not in use for a long time, please be sure to charge it at least once a month to protect the battery. The service life of battery of Melting and Filling Gun will be shortened when it is in a low battery state for a long time or when it leaves the charging base for a long time.

4) Temperature:

When the temperature is preset, the display screen shows the preset temperature value. About 1s after the temperature preset, the OLED screen will display the real-time temperature inside heating chamber.

When the Melting and Filling Gun is in the heating state, the temperature indicator will simultaneously display the current temperature.

5) Charging base:

Firstly, connect the power adapter plug to the power adapter as shown in Figure 2. Then connect the power adapter to the charging base as shown in Figure 3 and connect the power adapter to a standard socket.

Place the Melting and Filling Gun correctly on the charging base as shown in Figure 4, so that the charging connector under the Melting and Filling Gun can be reliably connected to the output connector of the charging base. When the Melting and Filling Gun is properly connected to the charging base, the LED charging indicator on the base will be on constantly. If the LED is flashing or not lit, please check all the cables carefully. There are charging status indicators on the charging base. When the Melting and Filling Gun is not placed on the charging base, the indicator will flashes in yellow and green alternately. When the Melting and Filling Gun is placed on the charging base, if the charging is being charged, the yellow indicator will be on constantly. When the battery is full, the yellow indicator will be off and the green indicator will be on constantly.

Notes: After receiving the device, please charge it immediately. Before use, please be sure that battery is fully charged. When the device is fully charged, the battery level of the Melting and Filling Gun LED display screen is the highest. After the battery runs out, the time of battery charging takes at least 2 hours and 30 minutes.



Figure 2 Installation of power adapter



Figure 3 Connection to power supply



Figure 4 Charging



Figure 5 Gutta-percha loading slot



Figure 6 Heat insulation hood



Figure 7 Gutta-percha injection needle

6) Gutta-percha loading slot:

⚠ **Note:** Only gutta-percha can be loaded into it for a time.

7) Heat insulation hood:

The design of heat insulation hood is to protect the oral soft tissue and lip from scalding.

⚠ **Note:** Before being used to different patients or before each use, please clean, disinfect and sterilize the heat insulation hood.

8) Gutta-percha injection needle

Before use, the gutta-percha injection needle and the MaxFill-G must be connected and tightened with the wrench provided by our company to prevent the injection needle from falling off or the gutta-percha leakage during use. But do not to screw too tight. Here we provide a variety of injection needles with different sizes (Please refer to Table 2), and the injection needles can be pre-bent depending on the application. (Note: Store unused gutta-percha injection needles in a sealed environment, as the gutta-percha injection needle are made of silver and may discolor due to oxidation caused by long-term exposure to air). Please use the wrench provided by the company to connect, disassemble and pre-bend the gutta- percha injection needle.

Note: When replace the gutta-percha injection needle, please first power off and wait for 5 minutes. Only after the Melting and Filling Gun and gutta-percha injection needle cool down, the replacement can start. When the gutta-percha injection needle is still hot, to avoid scalding, please do not pre-bent or replace the gutta-percha injection needle.

⚠ **Warning:** Before being used to different patients or before each use, please clean, disinfect and sterilize the gutta-percha injection needle. It is recommended that users follow manufacturer's written instructions to properly disinfect the device; the Melting and Filling Gun cannot be autoclaved. Do not autoclave the Melting and Filling Gun and charging base or place them in chemical disinfectants.

9) Wrench:

The wrench is used to tighten the gutta-percha injection needle and its connection to Melting and Filling Gun. After tighten the gutta-percha injection needle, the needle can be bent to any suitable angle with wrench. Do not use other instruments to pre-bend the needle other than the wrench provided by manufacturers.



Figure 8

10) Cleaning brush:

When cleaning the heating chamber with a cleaning brush, first set the preset temperature of the Melting and Filling Gun to 200 ° C, then insert the cleaning brush into the back of the Melting and Filling Gun, and then push it hard to ensure that the cleaning brush is removed from the front of the heating chamber. Do not remove the cleaning brush from the back of the Melting and Filling Gun. When cleaning, you can repeat the cleaning for several times to ensure that the heating chamber is well cleaned.

1.6 Device includes (see packing list)

1.7 Introduction and scope of application

1.7.1 Features:

a) Symmetrical two-sided display and operation button design for left or right hand operation.

b) Cordless design for Melting and Filling Gun effectively broadens the operation space.

c) Sensitive temperature control, simple display, and convenient operation; Press temperature setting button to set suitable working temperature.

d) Four preset temperatures are for option: 150℃ , 180℃ , 200℃ , 230℃

e) Safe protecting system. If there is no operation for 10 minutes, the Melting and Filling Gun will automatically shut down.

1.7.2 Scope of application:

Only used in endodontic filling with gutta-percha or root canal sealant. MaxFill-G is equipped with gutta-percha injection needle and heat insulation hood to heat up and soften gutta-percha to backfill root canal.

1.8 Product specifications

Sizes	Melting and Filling Gun	31mm*146mm*115mm
	Charging base	93mm*155mm*68mm
Weight	Melting and Filling Gun	169g
	Charging base	233g
	Power adapter	168g
Software version	1.0.0	

1.9 Technical parameters

Classification	Class Ⅱ (AC/DC power adapter)	
Optional preset temperatures	150℃ , 180℃ , 200℃ , 230℃	
Time consumption for charging	About 2.5h (First charging needs 3 h)	
Power supply	Input	100-240V AC 50/60Hz 800mA
	Output	DC 15V/1.6A
Battery capacity	Chargeable battery	1900mAh

1.10 Environmental parameters

Working condition	Temperature	+5°C - +40°C
	Humidity	30% - 75%
	Air pressure	70kPa - 106kPa

1.11 Storage and transport

1.11.1 The device should be handled carefully and lightly. Be sure that it is far from the vibration, and is installed or kept in a cool, dry, and ventilated place.

1.11.2 Do not store the device together with the articles that are combustible poisonous, caustic, or explosive.

1.11.3 The device should be stored in a room where the relative humidity is 10% - 93%, the air pressure is 70kPa - 106kP, and the temperature is -20°C - +55°C .

1.11.4 Please avoid the device from strong shock or vibration during transport. And please handle it carefully.

1.11.5 Please do not mix the device with hazardous articles during transport.

1.11.6 Please avoid the device from sun, rain, and snow during transport.

2 Installation and disassembly method of accessories

2.1 Connection of power adapter

Connect the output point of power adapter to the charging base, and connect the input point to the socket that meets the standard of this power adapter. Please install in accordance with the procedures in Figure 2, Figure 3, and Figure 4.

2.2 Installation, disassembly and pre-bent of gutta-percha injection needle

⚠ **Note:** In order to prevent from scalding, when replace the gutta-percha injection needle, please first power off and wait for 5 minutes. Only after the heating point cools down, the replacement can start.

2.2.1 Power off the device and wait for 5 minutes until the Melting and Filling Gun cools down. And then use wrench to disassemble the injection needle in counter-clockwise direction.

2.2.2 Place the used needle in the dedicated container.

2.2.3 Select needed gutta-percha injection needle (20ga, 23ga or 25ga. Please refer to Table 2 for details.), and tighten the injection needle to the Melting and Filling Gun in clockwise direction. Please be cautious not to over tighten.

Table 2 Models of gutta-percha injection needles

Model	Gauge	Length
20G 22mm	20G	22mm
20G 24mm	20G	24mm
20G 28mm	20G	28mm
23G 24mm	23G	24mm
23G 28mm	23G	28mm
25G 24mm	25G	24mm

2.2.4. Use wrench to bend the needle to needed angle.

2.3 Installation and disassembly of heat insulation hood

Start installation and disassembly from head part of the Melting and Filling Gun.

2.4 Removal and replacement of battery

When replace the battery, first loosen the fixing screw with a screwdriver, then remove the battery cover, next remove the old battery, replace it with a new one, and finally cover the battery cover and tighten the screws.

2.5 Installation and disassembly of pushing ram

The pushing ram can only be plugged in or unplugged from tail part of the Melting and Filling Gun.



3 Operation method

⚠ **Warning:** DO NOT pull out the pushing ram before it cools completely.

⚠ **Note:** During use, please do not contact the heating part of the Melting and Filling Gun. Before use, remember to install the heat insulation hood to prevent users or patients from scalding.

3.1 Choose gutta-percha injection needle

Choose suitable gutta-percha injection needle (20ga, 23ga or 25ga) according to the situation of patient. And tighten the gutta-percha injection needle and handpiece (Note: not too tight). Note: the 23ga and 25ga rotating type gutta percha injection needle can rotate to suitable angle within the range of 360° in clockwise direction and counter- clockwise direction. And you can also use wrench to pre-bend the needle and adjust it to a better operation angle as per your needs.

⚠ **Warning:** When install the gutta-percha injection needle, please be sure that the device is off and the head part of the device is cooling down. (About 5 minutes after shutdown of the Melting and Filling Gun, the head part of it can cool down to the temperature that allows people to touch.)

3.2 Choose the gutta-percha

Choose suitable gutta-percha for the device. Before loading it into the loading slot, pull the pushing ram back (do not pull out) to empty the loading slot, and then tilt the head of the gun down. After tilting the head part for an certain angle, put the gutta-percha into the loading slot, and then use the pushing ram to push the gutta-percha into the heating chamber completely (Note: only one gutta-percha stick can be placed at a time). When the gutta-percha completely enters the heating chamber, the black marker circle of the pushing ram will fully advance into the gun. Failure to fully fit the gutta-percha into the heating chamber will result in function failure of the device.

3.3. Power on

After powering on with long press on "ON/OFF" button, the device will automatically heat up to the preset temperature. If you want to change the preset temperature, please continuously press the temperature control button until the display screen displays the needed temperature value. After each press, the temperature will change once in the sequence of 150℃ , 180℃ ,200℃ , 230℃ . And it will back to 150℃ when you press the button while at 230℃ . During operation, please refer to Table 1 Recommended temperature setting to set suitable temperature.

One second after setting suitable temperature, the display screen will automatically skip to display the actual heating temperature. And it will heat up until reach the preset temperature. Pull the trigger to push the pushing ram forward until there is a small amount of extrusive gutta- percha in the needle.

⚠ **Note:** The displaying temperature is the temperature inside the heating chamber.

3.4. Canal obturation

Install the heat insulation hood at the connecting part of gutta-percha injection needle and Melting and Filling Gun, and wipe the filling material from the needle with gauze and alcohol. Note: The needle is hot at this time, and the injection needle starts filling from the bottom of the root canal to reduce or avoid the generation of bubbles. Place the needle at the bottom of the root canal. Pull the trigger to squeeze the gutta- percha, and slowly retract the needle until reach the crown hole.

⚠ **Warning:**

When the trigger is squeezed to fill the gutta-percha without retracting the needle, the injection needle may break. While the gutta-percha is still hot, use a medical vertical presser to squeeze down. If there are bubbles in the root canal, use a small amount of material to fill the root canal for many times. Use a little more material for each filling and use vertical presser to press it down.

3.5. Replacement of gutta-percha

When the trigger is pushed forward to push the push ram to make a "click" sound. it indicates that the gutta-percha in the Melting and Filling Gun has been used up. And it is necessary to load a new gutta-percha stick in time. When loading another gutta-percha stick, make sure the filling gun has cooled to room temperature. When the previous gutta- percha has been completely squeezed out, then according to step 2, reselect the appropriate gutta-percha for loading.

⚠ **Warning:**

Do not replace the gutta-percha stick in the heated state, otherwise it may cause scalding or damage the Melting and Filling Gun.

3.6. After operation

The remaining materials in the heating chamber must be cleaned, and the relevant accessories must be cleaned, disinfected and sterilized. For details, see section 6.1

4 Charging instruction

4.1 Use corresponding charging base for charging: Connect the power adapter to the charging base, and connect to power supply. And then correctly place the Melting and Filling Gun in the charging base. When the Melting and Filling Gun is not placed on the charging base, the indicator will flashes in yellow and green alternately. When the Melting and Filling Gun is placed on the charging base, if the charging is being charged, the yellow indicator will be on constantly. When the battery is full, the yellow indicator will be off and the green indicator will be on constantly. Under normal situation, the charging takes about 2.5h.

4.2 The battery used in this product has no memory and can be used at any time or charged at any time.

4.3 Before first use of this device, please charge it at least for 3 hours.

5 Safety precautions

5.1 Do not use instruments other than the provided wrench to install, disassemble or pre-bent gutta-percha injection needle.

5.2 Do not knock or scratch the Melting and Filling Gun.

5.3 Do not place the Melting and Filling Gun near an electronic device, phone, radio or HD/satellite TV as these may affect the temperature control of the Melting and Filling Gun.

5.4 Keep heat carrier accessories such as Melting and Filling Gun, gutta-percha injection needle, heat insulation hood etc. under heating state away from inflammable and explosive materials.

5.5 Please keep the device clean before and after operation. Before each use, please clean, disinfect and sterilize the accessories such as gutta- percha injection needle, heat insulation hood and wrench.

5.6 Users should be equipped with adequate protection such as goggles, mask, etc. to prevent cross-infection.

5.7 The product should be in strict accordance with relevant operation specifications of medical authority and relative regulations. The product can only be operated by trained doctors or technicians.

5.8 Do not install, remove, or replace the heat insulation hood and injection needle under heating state. If you need to replace the injection needle, please first power off and wait for 5 minutes. Five minutes later, if the Melting and Filling Gun totally cools down, replace the injection needle.

5.9 The injection needle must be correctly installed to prevent from falling off or gutta-percha leakage during operation.

5.10 Do not use excessive force when pre-bending the injection needle to prevent the injection needle from breaking. When the injection needle is bent or worn, the gutta-percha flowing ability may be deteriorated, and the operator should replace the new injection needle in time according to the clinical condition;

5.11 Refine is specialized in producing medical instrument. We are only responsible for the safety on the following conditions;

a) The maintenance, repair, and modification are made by the manufacturer or the authorized dealers.

b) The charged components are original of "Refine" and operated according to instruction manual.

5.12 The applied parts of the device are intended to supply heat to the patient, and the maximum temperature may reach 123.5℃ , please be careful about this.

5.13 The device must not be used in MRI environment for the device is easily affected by the electromagnetic emission and would not work or work normally.

5.14 When you meet circumstances where the main unit expires, the misuses lead to the short circuit of the circuit board or accidentally dropping the device results in the damage of components, the device should no longer be reused.

5.15 Any serious incident that has occurred in relation to the medical device should be reported to the manufacturer and the competent authority of the regions or countries in which the user and/or patient is established.

6 Maintenance

6.1 cleaning, disinfection and sterilization

After use, squeeze out all the residual materials inside heating chamber, power off the device, pull the pushing ram out of Melting and Filling Gun from the back side, and remove the material on the top of pushing ram.

For the reprocessing methods, please follow the attached "Reprocessing instructions of cleaning, disinfection and sterilization"

•Recommended sterilization cycles of heat insulation sleeve for injection needle, heat insulation hood and wrench: 300 cycles

Recommended sterilization cycles of injection needle: 50 cycles.

6.1.1 Cleaning of charging base and Melting and Filling Gun

The charging base and the surface of Melting and Filling Gun can be wiped with a soft towel with a small amount of neutral detergent or disinfectant alcohol.

6.1.2 Heat insulation hood

Before first use and before used to different patients, please clean, disinfect and sterilize it. It is recommended to execute steam sterilization after washing with water or washing in ultrasonic cleaner.

6.1.3 Gutta-percha injection needle

After being used to each patient, please change the needle in time. When there is found or suspected damage to the needle, place it in a fixed recycling container.

6.1.4 Cleaning of heating chamber

When removing the residue inside the heating chamber and the loading slot, set the temperature of the device to 200 ℃ , and then power off the device after squeezing all the residual materials out. After pulling the pushing ram out from back part, insert the supplied cleaning brush from the back of the device and pull it out from the front part of the Melting and Filling Gun. Please take care not to add any cleaning agent or chemicals to the cleaning brush.

6.1.5 Pushing ram

Use sterile alcohol and gauze to remove any visible residue.

6.1.6 For the reprocessing method of the gutta-percha injection needle, heat insulation hood and the wrench, please follow the attached "Reprocessing instructions of cleaning, disinfection and sterilization"

6.1.7 If the other accessories need to be cleaned or disinfected, please use gauze to pick up a small amount of water or disinfectant to wipe the surface. Do not soak those accessories in the cleaning solution.

6.1.8 Do not use volatile and diffluent solvents for cleaning, which will damage the surface of the device or cause the markings on the machine to fade.

6.2 Daily maintenance

When the device is not used, please turn off the power and unplug the power supply plug.

If the Melting and Filling Gun is in a low battery state for a long time, the service life of battery will be shortened. Please charge it in time if the battery level is low. When the device is not used, please charge it for 1 hour once a month.

6.3 Repair of device

This product does not contain self-repairing spare parts. Repair should be carried out by a designated professional or special repair shop.

7 Troubleshooting

Fault	Cause	Solution
After pressing the "ON/OFF" button, the device is still off.	1. Inadequate battery power 2. Battery is damaged. 3. The charging interface is short-circuited, causing the lithium battery to enter a protection state; 4. Melting and Filling Gun is arnaged.	1. Connect to power supply to charge. Replace the battery. 2. Replace the battery. 3. Remove the substance that causes the short circuit, put the device into the charging base to charge, and then the device will return to normal. 4. Contact local distributor or manufacturer.
Gutta-percha cannot flow out from the needle	1. The push ram has been pushed to the end, and gutta-percha has run out . 2. The pushing ram seal ring is damaged. 3. The injection needle is damaged and blocked	1. Pull back the pushing ram and load a new gutta -percha stick 2. Replace the pushing ram 3. Replace the injection needle
Automatic shutdown	If there is no operation for 10 minutes, the device will automatic powers off	Reboot
The pushing ram cannot be pulled out	The portion of the pushing ram that enters the interior of the heating chamber is fixed by the cooling of the gutta-percha.	1. Power on and set the temperature to 200 ° C. After the temperature reaches the set value, pull out the pushing rem back. 2. Contact your local dealer or our company.
Charging failure after connecting to power supply.	1. The power supply is not correctly connected; 2. The power supply is damaged, or the specification doesn't match. 3. There are impurities on the contact thimble of charging base.	1. Unplug and reconnect. 2. Replace the battery. 3. Wipe the thimble with alcohol, dry it, and reconnect.
The service time after each charging is shortened.	The battery capacity becomes smaller.	Send to the repair center.
ERROR code appears on display screen.	The heating chamber is damaged.	1. Send to the repair center. 2. Contact local distributor or manufacturer.

If the problem still cannot be solved, please contact your local dealerer or company.

7.1 When the pushing ram is in the Melting and Filling Gun, please do not push or pull the pushing ram vigorously. When the gutta-percha is heated up to the preset temperature, the pushing ram should be pushed by pulling the trigger for multiple times. If the pushing ram does not move, try to push it manually with a slight force, and try to pull the trigger.

7.2 Please refer to the recommended temperature to set the preset temperature.

7.3 To remove all remaining material, please first remove the injection needle, and then pull the trigger to squeeze out all the residual material in the heating chambers. Be careful not to touch the head of the Melting and Filling Gun to avoid scalding. Power off, cool it down slightly, and push the pushing ram down.

8 Disposal and Scrapping

After the device is out of its service life, you must not discard it in domestic household waste. Please comply with the Waste Electrical and Electronic Equipment (WEEE) directives and the medical waste disposal regulations of your country. According to the WEEE Directive, Refine or its dealers will ensure that information needed to calculate the financial obligations with respect to EEE products will be provided as required.

Components which could easily contact to the biological sources and cause biological hazards shall detached from the main unit and reprocessed according to the reprocessing treatment before the disposal and scrapping.

MaxFill-P

Introduction

Thank you for purchase MaxFill-P Heating and Packing Instrument developed by Guilin Refine Medical Instrument Co., Ltd., a Hi-tech enterprise developing, manufacturing, and selling dental instruments. Refine has excellent Quality Control System. To guarantee correct and safe operation, please read this Instruction Manual carefully before use.Depending on the level of risk involved, safety instructions are classified under the following indications:

⚠ **Danger:** (always referred to personal injury)

⚠ **Warning:** (referred to possible damage to property)

1 Product introduction

1.1 Intended use

It is used to provide heat to the working tip, cut the gutta-percha point, and soften and pressurize the gutta-percha.

1.2 Patient target groups:

Adults and Pediatrics.

1.3: Intended users:

The product is intended for use in hospitals and dental clinics only. The user must be professionally trained and qualified dentists.

1.4 Applied parts

Cone head, gutta-percha tip, heat insulation sleeve.

1.5 Diagram of components and control buttons

Figure 1-0 Matchine and components schematic



Figure 1-1 Preset temperature

1.5.1 "ON/OFF" button:

Under shutdown state, shortly press "ON/OFF" button to start the device.

Under shutdown state, long press "ON/OFF" button to start the device and change the direction of screen display, that is to say, the direction of display can be change to adapt to the operation in left hand or right hand.

Under ON state, long press "ON/OFF" button to shut down the device. (Time for long press is about 1s.)

Note: If there is no operation for 10 minutes, the Heating and Packing Instrument will automatically shut down.

Under ON state, shortly press "ON/OFF" button to change the preset temperature of tip. The preset temperature will change to the next with the sequence 150℃ , 180℃ , 200℃ , 230℃ after each press. And then go back to 150℃ after short press at temperature of 230℃ .

1.5.2 Heating button:

Under the ON state, connect the tip, and press Heating button to start heating. Release the Heating button to stop heating, followed by the fall of tip temperature.

Note: If press and hold the Heating button for more than 10 seconds, the device will stop heating. If need to continue heating, please release the Heating button and press again.

1.5.3 Battery level:

The actual power of the battery is displayed in real time on the screen. When the battery is fully charged, the power of the OLED display is displayed as five grids. When the battery level is one grid, it indicates that the battery is low and needs to be charged in time. When the battery level is zero, it indicates that the battery is exhausted and that the battery is very low and needs to be charged immediately. Note: During normal use, try not to let the battery level reduced to space status (completely no power) before charge, which will shorten the service life of battery.

⚠ **Warning:**

If the device has not been used for more than one month, the battery needs to be recharged. If the device is not in use for a long time, please be sure to charge it at least once a month to protect the battery. The service life of battery of Heating and Packing Instrument will be shortened when it is in a low battery state for a long time or when it leaves the charging base for a long time.

1.5.4 Temperature:

When the temperature is preset, the display screen shows the preset temperature value. About 1s after the temperature preset, the OLED screen will display the real-time temperature of the tip. When the Heating and Packing Instrument is in the heating state, the temperature indicator will simultaneously display the current temperature of the tip.

1.5.5 Charging base:

Firstly, connect the power adapter plug to the power adapter as shown in Figure 2. Then connect the power adapter to the power connecting hole on the charging base as shown in Figure 3 and connect the power adapter to a standard socket. Place the Heating and Packing Instrument correctly on the charging base as shown in Figure 4, so that the charging connector under the Heating and Packing Instrument can be reliably connected to the output connector of the charging base. When the Heating and Packing Instrument is properly connected to the charging base, the LED charging indicator on the base will be on constantly. If the LED is flashing or not lit, please check all the cables carefully.

There are charging status indicators on the charging base. When the Heating and Packing Instrument is not placed on the charging base, the indicator will flashes in yellow and green alternately. When the Heating and Packing Instrument is placed on the charging base, if the charging is being charged, the yellow indicator will be on constantly. When the battery is full, the yellow indicator will be off and the green indicator will be on constantly.

Notes: After receiving the device, please charge it immediately. Before use, please be sure that battery is fully charged. When the device is fully charged, the battery level of the Heating and Packing Instrument led display screen is the highest. After the battery runs out, the time of battery charging takes at least 2 hours and 30 minutes.



Figure 2 Installation of power adapter



Figure 3 Connection to power supply



Figure 4 Charging

1.6 Device includes （see packing list）

1.7 Introduction and scope of application

1.7.1 Features:

a) The display can be set to both right and left sides, to meet the needs of both left-hander and right-hander.

b) Cordless design for Heating and Packing Instrument effectively broadens the operation space.

c) Sensitive temperature control, simple display, and convenient operation; Press temperature setting button to set suitable working temperature.

d) Four preset temperatures are for option: 150℃ , 180℃ , 200℃ , 230℃ .

e) If there is no operation for 10 minutes, the Heating and Packing Instrument will automatically shut down.

1.7.2 Scope of application:

Used in the root canal obturation stage in endodontic treatment.

1.8 Product specifications

Size	Heating and packing instrument	24mm*158mm*24mm
	Charging base	92mm*154mm*66mm
Weight	Heating and packing instrument	82g
	Charging base	208g
	Power adapter	168g
Software version	1.0.0	

1.9 Technical parameters

Classification	Class II (AC/DC power adapter)	
Optional preset temperatures	150℃ , 180℃ , 200℃ , 230℃	
Time consumption for charging	About 2.5h	
Power supply	Input	AC100V-240V 50/60Hz 800mA
	Output	DC15V/1.6A
Battery capacity	Chargeable battery	1900mAh

1.10 Environmental parameters

Temperature: +5℃ ~ +40℃ ; Humidity: 30% - 75% ; Air pressure: 70kPa - 106kPa

1.11 Storage and transport

1.11.1 The device should be handled carefully and lightly. Be sure that it is far from the vibration, and is installed or kept in a cool, dry, and ventilated place.

1.11.2 Do not store the device together with the articles that are combustible poisonous, caustic, or explosive.

1.11.3 The device should be stored in a room where the relative humidity is 10% - 93%, the air pressure is 70kPa - 106kP, and the temperature is -20℃ ~ +55℃ .

1.11.4 Please avoid the device from strong shock or vibration during transport. And please handle it carefully.

1.11.5 Please do not mix the device with hazardous articles during transport.

1.11.6 Please avoid the device from rain, rain, and snow during transport.

2 Installation and disassembly method of accessories

2.1 Connection of power adapter

Connect the output point of power adapter to the charging base, and connect the input point to the socket that meets the standard of this power adapter. Please install in accordance with the procedures in Figure 2, Figure 3, and Figure 4. (Note: The installation in Figure 2 had been finished before delivery.)

2.2 Installation and removal of tip

2.2.1 After turning off the power switch, you can directly pull the tip off the Heating and Packing Instrument.

2.2.2 Place the sweet tip in a certain container and disinfect it.

2.2.3 Select the desired work tip and the hexagonal plug on the tip (as indicated by the red arrow in Figure 5). When installing the work tip as shown in Figure 6, you can select the appropriate direction according to the usage to insert the tip into the Heating and Packing Instrument.

2.2.4 Install the heat insulation sleeve to the tip as shown in Figure 7, to prevent scalding patient’ s mouth during operation.

2.2.5 Under ON state, if the tip hasn’ t been installed or is in poor connection, there would be an error code on display screen as shown in Figure 8.



Figure 5 Tip



Figure 6 Installation of tip



Figure 7 Installation of heat insulation sleeve



Figure 8 Error code

Table 2 Model of tips

Model	Tip Size(mm)	Taper
3504	0.35	0.04
4004	0.40	0.04
4504	0.45	0.04
5004	0.50	0.04
5506	0.55	0.06
5508	0.55	0.08
5510	0.55	0.10
6012	0.60	0.12
5508L	0.55	0.08

2.3 Installation and replacement of battery

When replacing the battery, as shown in Figure 9, first rotate the battery barrel counterclockwise to remove the battery tube, then take the old battery out of the battery tube, replace it with a new one, and finally tighten the battery tube clockwise according to the corresponding thread.Note: When removing the battery, the screw under the battery barrel (pointed by the arrow in Figure 9) does not need to be unscrewed,just push the connector slightly inward to remove the battery.



Figure 9 Replacement of battery

⚠ **Warning:** Improper replacement of lithium batteries may result in unacceptable risks, so only batteries provided by the manufacturer can be used and the replacement of lithium batteries must be performed by trained personnel. Do not disassemble the battery without authorization, do not squeeze or shake the battery, otherwise it may cause battery leakage.

3 Operation method

3.1 According to the situation of patient, select suitable tip and install it. When installing the tip, chose a suitable angle to install the tip. Danger:Don’ t turn on the device when installing the tip, to prevent scalding the user by mistakenly pressing the heating button.

3.2 After pressing the "ON/OFF" button, the display screen of Heating and Packing Instrument lights up and display the preheating temperature and power status.

3.3 According to the actual situation, lightly press the temperature setting button, and select suitable preheating temperature as per the instruction on display screen.

3.4 During operation, lightly press the heating button so as to heat up to the preset temperature, soften and pressurizing the gutta-percha with careful, continuous and stable motion with the help of vertical pressurizer.

⚠ **Note:** The continuous heating time on gutta-percha cannot exceed 4s, or there would be risk of scalding.

3.5 After operation, please clean, disinfect, and sterilize the tip.The specific method is shown in Chapter 6.1.

4 Charging instruction

4.1 Use the corresponding charging base for this device. Connect the power adapter with the charging base, connect the power supply, and then correctly place the Heating and Packing Instrument into the charging base.

4.2 The battery used in this product has no memory and can be used at any time or charged at any time.

4.3 Before the use of this device, please charge it at least for 3 hours.

5 Safety precautions

5.1 Do not polish the tip.

5.2 Do not knock or scratch the Heating and Packing Instrument.

5.3 Do not place the Heating and Packing Instrument near an electronic device, phone, radio or HD/satellite TV as these may affect the temperature control of the Heating and Packing Instrument.

5.4 Keep the heating pressurizer, tip, etc. under heating state away from inflammable and explosive materials.

5.5 Please keep the device clean before and after operation. Before each use, please disinfect tip and its accessories.

5.6 Users should be equipped with adequate protection such as goggles, mask, etc. to prevent cross-infection.

5.7 The product should be in e-strict accordance with relevant operation specifications of medical authority and relative regulations. The product can only be operated by trained doctors or technicians.

5.8 Do not install, remove, or replace the tip under heating state. Please power off before replace the tip.

5.9 The tip must be correctly installed to prevent it from falling off.

5.10 When the working tip is bent or worn, it will cause uneven heating. The operator should replace the tip in time according to the clinical conditions.

5.11 After operation, please turn off the power immediately. Refine is specialized in producing medical instrument. We are only responsible for the safety on the following conditions:

a) The maintenance, repair, and modification are made by the manufacturer or the authorized replace the tip.

b) The charged components are original of "Refine" and operated according to instruction manual.

5.12 The applied parts of the device are intended to supply heat to the patient, and the maximum temperature may reach 103.7℃ , please be careful about this.

5.13 The device must not be used in MRI environment for the device is easily affected by the electromagnetic emission and would not work or work normally.

5.14 When you meet circumstances where the main unit expires, the misuses lead to the short circuit of the circuit board or accidentally dropping the device results in the damage of components, the device should no longer be reused.

5.15 Any serious incident that has occurred in relation to the medical device should be reported to the manufacturer and the competent authority of the regions or countries in which the user and/or patient is established.

6 Maintenance

6.1 Cleaning, disinfection and sterilization

6.1.1 For the reprocessing methods, please follow the attached "Reprocessing instructions of cleaning, disinfection and sterilization". Recommended sterilization cycles of heat insulation sleeve and tip: 300 cycles

6.1.2 If the other accessories need to be cleaned or disinfected, please use gauze to pick up a small amount of water or disinfectant to wipe the surface. Do not soak.

6.1.3 Do not use volatile and diffluent solvents for cleaning, which will damage the surface of the device or cause the markings on the machine to fade.

6.2 Daily maintenance

6.2.1 When the device is not used, please turn off the power and unplug the power supply plug.

6.2.2 If the Heating and Packing Instrument is in a low battery state for a long time, the service life of battery will be shortened. Please charge it in time if the battery level is low.

6.2.3 When the device is not used, please charge it for 1 hour once a month.

6.3 Repair of device

This product does not contain self-repairing spare parts. Repair should be carried out by a designated professional or special repair shop.

7 Troubleshooting

Fault	Cause	Solution
No indications, no response	1. Inadequate battery power 2. Battery is damaged. 3. The charging interface is short-circuited, causing the lithium battery to enter a protection state; 4. Heating and Packing Instrument is damaged.	1. Connect to power supply to charge. Replace the battery. 2. Replace the battery. 3. Remove the substance that causes the short circuit, put the device into the charging base to charge, and then the device will return to normal; 4. Contact local distributor or manufacturer.
Automatic shutdown	If there is no operation for 10 minutes, the device will automatically powers off.	Reboot
Tip works abnormally	1. The tip is damaged. 2. Malfunction of main unit	1. Replace the tip 2. Send it to the repair center.
Charging failure after connecting to power supply	1. The power supply is not correctly connected; 2. The power supply is damaged, or the specification doesn’t match. 3. There are impurities on the contact thimble of charging base.	1. Unplug and reconnect. 2. Replace the battery. 3. Wipe the thimble with alcohol, dry it, and reconnect.
The service time after each charging is shortened	The battery ages and the battery capacity become smaller.	Contact local distributor or manufacturer to buy new batteries for replacement.
OPEN code appears on display screen	1. The tip is damaged. 2. The tip is not installed. 3. The tip is not well installed.	1. Replace the tip. 2. Install the tip. 3. Unplug the tip, and reconnect.

If the problem still cannot be solved, please contact your local dealer or our company.

8 Standard icons

SN	Serial number		Refer to instruction manual/booklet
	Manufacturer		Date of manufacture
	Type B applied part		Class II equipment
	Power switch	IPX0	Ordinary equipment
	For indoor use only		Waste electrical and electronic equipment
	Sterilizable in a steam sterilizer (autoclave) at 134℃	DC 15V	DC 15V
	Caution, hot surface		Keep dry
	Recovery		Fragile,handle with care
	Caution	106kPa 70kPa	Atmospheric pressure limitation: 70kPa-106kPa
93% 10%	Humidity limitation: 10%-93%	55℃ -20℃	Temperature limit: -20℃ - +55℃
MD	Medical device	CE 0123	CE marking with identification number of the Notified Body

9 Contraindications

1. People who are allergic to known natural latex and metals such as stainless steel, silver, copper, etc. are prohibited to use this device.
2. The patient with hemophilia is forbidden to use this device.
3. The patients with heart pacemaker are forbidden to use this device.
4. The dentists with heart pacemaker are forbidden to use this device.
5. Heart disease patients, pregnant women and children should be cautious to use the equipment.

10 After-sales service

Service life: 10 years.

Since the date of sales, if the device cannot work normally for during the warranty period. Please refer to the Warranty Card for warranty period and warranty scope.

11 Environment protection

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

⚠ **Note:**

1 Without Refine agreement and authorization, private modification of device may result in the electromagnetic compatibility problem of that device or other devices.

2 The design and test of Heating and Packing Instrument complies with the related operation regulations of electromagnetic compatibility.

12 Statement

Refine reserves the right to change the design of the equipment, the technique, fittings, instruction manual and the content of the original packing list at any time without further notice. The pictures are only for reference. The final interpretation rights belong to Guilin Refine Medical Instrument Co., Ltd.

13 EMC - Declaration of conformity

13.1 Instructions for use

THE WE EQUIPMENT or WE SYSTEM is use in hospitals or dental clinics.

⚠ **Warning:**

Don’ t near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbance is high.

⚠ **Warning:**

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

⚠ **Warning:**

Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

⚠ **Warning:**

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

⚠ **Note:**

The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

List of all cables

No	Name	Length	Shielded or not	Detachable or not	Note
1	Power adapter output line	1.8m	No	No	/

Replaceable accessories

No	Name	Model	Manufacturer	Connection method	Note
1	Power adapter	UE24WCPJ-1501 60SPA	/	plug	/
2	Battery	ICR 18500	/	plug	/

Performance of the equipment

MaxFill-G：

Heat up and soften gutta-percha, and fill the gutta-percha into the root canal after preparation. The MaxFill-G has four preset temperatures for option: 150℃ , 180℃ , 200℃ , 230℃ . When the me equipment essential performance is lost or degraded due to em disturbances, the doctor should immediately stop using it to ensure that there is no treatment error. And then remove the source of disturbances or adjust the direction or position of me equipment to ensure me equipment can be used in normal performance condition.

MaxFill-P：

used to provide heat to the working tip, cut the gutta-percha point, and soften and pressurize the gutta-percha. The MaxFill-P has four preset temperatures for option: 150℃ , 180℃ , 200℃ , 230℃ . When the me equipment essential performance is lost or degraded due to em disturbances, the doctor should immediately stop using it to ensure that there is no treatment error. And then remove the source of disturbances or adjust the direction or position of me equipment to ensure me equipment can be used in normal performance condition.

13.2 Technical description

1. Portable and mobile RF communications equipment may affect the performance of equipment , use of equipment should be avoided strong electromagnetic interference, and do not closer to mobile phone, microwave oven, etc.

2. Use of equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

3. Except for the cables sold by manufacturers of as spare parts of internal components, the use of accessories and cables other than those specified or provided by this equipment may result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

4. Use of accessories, transducers and cables other than those specified or provided by the manufacturer together with equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

5、Guidance and manufacturer’ s declaration- electromagnetic emissions and Immunity

Table 1

Guidance and manufacturer’s declaration - electromagnetic emissions	
Emissions test	Compliance
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class A
Harmonic emissions IEC 61000-3-2	Not Applicable
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not Applicable

Table 2

Guidance and manufacturer’s declaration - electromagnetic Immunity		
Immunity test	IEC 60601-1-2 Test level	Compliance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air
Electrical fast transient/burst IEC 61000-4-4	± 2 kV power supply lines ± 1 kV signal input/output 100 kHz repetition frequency	± 2 kV power supply lines Not applicable 100 kHz repetition frequency
Surge IEC 61000-4-5	± 0.5 kV, ± 1 kV differential mode ± 0.5 kV, ± 1 kV, ± 2 kV common mode	± 0.5 kV, ± 1 kV differential mode Not applicable
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0.5 cycle At 0° , 45° , 90° , 135° , 180° , 225° , 270° and 315°. 0 % UT; 1 cycle and 70 % UT; 25/30 cycles: Single phase: at 0°. 0 % UT; 250/300 cycle	0 % UT; 0.5 cycle At 0° , 45° , 90° , 135° , 180° , 225° , 270° and 315°. 0 % UT; 1 cycle and 70 % UT; 25/30 cycles: Single phase: at 0°. 0 % UT; 250/300 cycle
Conducted RF IEC61000-4-6	3 Vr.m.s 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 Vr.m.s 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz
Radiated RF IEC61000-4-3	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz

NOTE UT is the a.c. mains voltage prior to application of the test level.

Table 3

Guidance and manufacturer’s declaration - electromagnetic Immunity					
	Test frequency (MHz)	Band (MHz)	Service	Modulation	IEC 60601-1-2 test level. (V/m)	Compliance level (V/m)
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)	385	380 - 390	TETRA 400	Pulse modulation 18 Hz	27	27
	450	430 - 470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	28	28
	710	704 - 787	LTE Band 13, 17	Pulse modulation 217 Hz	9	9
	745					
	780					
	810	800 - 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	28	28
	870					
	930					
	1720	1700 – 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	28	28
	1845					
	1970					
	2450	2400 – 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	28	28
	5240	5100 – 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	9	9
	5500					
	5785					

Table 4

Guidance and manufacturer’s declaration - electromagnetic Immunity				
Radiated RF IEC61000-4-39 (Test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields)	Test Frequency	Modulation	IEC 60601-1-2 Test Level (A/m)	Compliance level (A/m)
	30 kHz	CW	8	8
	134.2 kHz	Pulse modulation 2.1 kHz	65	65
	13.56 MHz	modulation	7.5	7.5

14 Disposal and Scrapping

After the device is out of its service life, you must not discard it in domestic household waste. Please comply with the Waste Electrical and Electronic Equipment (WEEE) directives and the medical waste disposal regulations of your country. According to the WEEE Directive, Refine or its dealers will ensure that information needed to calculate the financial obligations with respect to EEE products will be provided as required. Components which could easily contact to the biological sources and cause biological hazards shall detached from the main unit and reprocessed according to the reprocessing treatment before the disposal and scrapping.

Reprocessing instructions of cleaning, disinfection and sterilization

1. Beginning Work!

1.1 Please read these operating instructions carefully as they explain all the most important details and procedures. Please pay special attention to the safety precautions. Always keep this instruction close at hand.

1.2 To prevent injury to people and damage to property, please heed the corresponding directives.

1.3 The instructions in this manual are only applicable to the product which it was delivered with.

2. Introduction

2.1 These reprocessing instructions provide instructions for cleaning, disinfection, sterilization and packaging of manufacturer reusable products intended to be reprocessed in medical facilities.

2.2 The goal of reprocessing reusable products is to reduce bioburden and to achieve sterility of those products in order to eliminate the risk of product reuse related infection. Decisions regarding cleaning, disinfecting or sterilizing manufacturer’s medical and dental products are based on the potential risk of infection associated with their use.

2.3 It is recommended to use steam sterilization.

2.4 Remember that sterilization or high-level disinfection cannot be achieved unless the elements of the assembly are cleaned first.

2.5 If you find that the reprocessing instructions from the manufacturer seem to be inadequate, please inform manufacturer about those inadequacies.

2.6 We encourage you to report adverse events related to device reprocessing. Report such events directly to manufacturer.

3. Reprocessing - Instructions For Reusable Products

3.1 The instructions are binding for the reprocessing of the Gutta-percha Tip, Gutta-percha injection needle, heat insulation hood and the wrench (hereafter called "products") of manufacturer. When necessary, additional product-specific instructions are included with the product to provide additional information.

⚠ **Important: Before use, carefully read the operating instructions of the manufacturer instrument and devices with which the product will be used.**

3.2 Reusable products must be cleaned, disinfected and sterilized prior to first use. Reprocessing procedures have only limited implications to this device. The limitation of the numbers of reprocessing procedures is therefore determined by the function / wear of the device. From the processing side there is no maximum number of allowable reprocessing. The device should no longer be reused in case of damage or impaired function.

⚠ **In case of damage the product should be reprocessed before sending back to the manufacturer for repair.**

4. Preparation - Basic Principles

4.1 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.

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

5. Preparation at the Point of Use

Disconnect product. 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 products in a humid surrounding.

6. Transportation

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

7. Preparation for Decontamination

The products must be reprocessed in a disassembled state, as far as possible.

8. Pre-cleaning

Do a manual pre-cleaning, until the products are visually clean. Submerge the products 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.

9. 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.

Automated Cleaning:

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

Put the instrument into the machine on a tray. Connect the instrument with the WD by using suitable adapter and start the program:

4 min pre-washing with cold water (<40° C);

emptying

5 min washing with a mild alkaline cleaner at 55° C

emptying

3 min neutralising with warm water (>40° C);

emptying

5 min intermediate rinsing with warm water (>40° C)

Emptying

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

⚠ **Purified water shall be used for cleaning.**

⚠ **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.**

10. 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 product to achieve an A0 value of 3000.

Purified water shall be used for disinfection.

11. 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 products in drying cycle by using sterile compressed air.

12. Functional Testing, Maintenance

Visual inspection for cleanliness of the products and reassembling if required. 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 products have been maintained acc. to manufacturer’ s instruction.

13. Packaging

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

14. Sterilization

Sterilization of products by applying a fractionated pre-vacuum steam sterilization process (according to EN 285/EN 13060/EN ISO 17665) under consideration of the respective country requirements.

Minimum requirements: 3 min at 134 ° C (in fact 5 min at 134 ° C)

Maximum sterilization temperature: 137° C

Drying time:

For steam sterilization, we recommend a drying time of 15 to 40 minutes. Choose a suitable drying time, depending on the autoclave and load. Refer to the autoclave’ s instructions for use.

After sterilization:

a. Remove the product from the autoclave.

b. Let the product cool down at room temperature for at least 30 minutes. Do not use additional cooling.

Check that the sterilization wraps or pouches are not damaged.

⚠ **Flash sterilization is not allowed on human instruments.**

⚠ **The manufacturer assumes no responsibility for the use of other sterilization procedures (e.g. ethylene oxide, formaldehyde and low temperature plasma sterilization).** In such cases, please observe the respective valid standards (EN ISO 14937/ANSI AAMI ISO 14937 or the procedure-specific standard) and verify the suitability and effectiveness in principle of the procedure (if necessary, including investigations on sterilizing agent residue), taking into account the specific product geometry as part of the validation.

15. Storage

Storage of sterilized products in a dry, clean and dust free environment with a relative humidity of 10% to 93%, an atmospheric pressure of 70KPa to 106KPa, and a temperature of -20 ° C to +55 ° C; refer to label and instructions for use. 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 7days. If it is exceeded, it should be reprocessed before use.

16. Service Life

The products have been designed for a large number of sterilization cycles. The materials used in their manufacture were selected accordingly. However, with every renewed preparation for use, thermal and chemical stresses will result in aging of the devices. For this product, the recommended number of reprocessing cycles is no more than 50.

⚠ **The use of ultrasound baths and strong cleaning and disinfection fluids (alkaline pH>9 or acid pH<5) can reduce the life span of devices. The manufacturer accepts no liability in such cases.**

⚠ **The devices may not be exposed to temperatures above 137 ° C.**

It is the duty of the user to ensure that the reprocessing processes including resources, materials and personnel are capable to reach the required results. State of the art and rational law requiring these processes and included resources to be validated and maintained properly.

Note: We reserve the rights to change the design of the equipment, the technique, fittings, the instruction manual and the content of the original packing list at any time without notice. If there are some differences between blueprint and real equipment, take the real equipment as the norm.

Shelf life: 10 years, the date of manufacture see product label.

Guilin Refine Medical Instrument Co., Ltd.

No.8-3, Information Industrial Park, High-Tech Zone, Qixing District, 541004 Guilin, Guangxi, PEOPLE’ S REPUBLIC OF CHINA

Tel: +86-773-7796686 // Email:refine@refine-med.com // Website: http://www.refine-med.com

MedNet EC-REP C IIb GmbH, Borkstrasse 10, 48163 Münster, Germany