

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 after preparation.

#### 1.2 Patient target groups:

Adults and Pediatrics.

#### 1.3 Intended users:

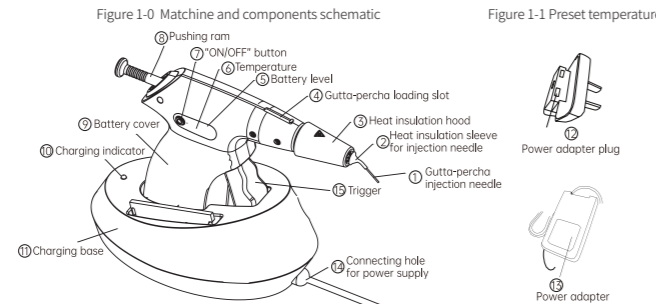
The product is intended for use in hospitals and dental clinics only. The user must be professionally trained and qualified dentists.

#### 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.



#### 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°C, 180°C, 200°C, 230°C as shown in Figure 1, and back to 150° when you press the button in 230°C.

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

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.

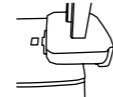


Figure 2 Installation of power adapter



Figure 3 Connection to power supply



Figure 4 Charging

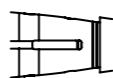


Figure 5 Gutta-percha loading slot

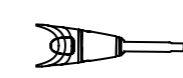


Figure 6 Heat insulation hood

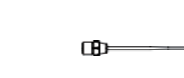


Figure 7 Gutta-percha injection needle

#### 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.

#### 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°C, 180°C, 200°C, 230°C
- 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°C, 180°C, 200°C, 230°C	
Time consumption for charging	About 2.5h (First charging needs 3 h)	
Power supply	Input	100-240V AC 50/60Hz 800mA
	Output	DC15V/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 - 106kPa, 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.

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.

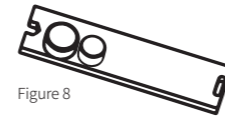


Figure 8

#### 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°C, 180°C, 200°C, 230°C. And it will back to 150°C when you press the button while at 230°C. 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 trigger.

**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 filling 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°C. 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 °C, 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.

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