

**COXO®**

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# User Manual



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C-FILL   
Endodontic Obturation Systems



Recommended separation distances between portable and mobile RF communications equipment and the model C-FILL			
The model C-FILL is intended for use in electromagnetic environment in which radiated RF disturbances is controlled. The customer or the user of the model C-FILL can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the model C-FILL is recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150kHz to 80MHz $d=1.2 \times \sqrt{P}$	80MHz to 800MHz $d=1.2 \times \sqrt{P}$	800MHz to 2,7GHz $d=2.3 \times \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) accordable to the transmitter manufacturer.			
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.			
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

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# 1 Safety



## Warning:

Read the safety warnings carefully before using this instrument.

- 1) The instrument must be used within the scope mentioned in the manual, if the user does not follow the instructions or use this instrument for other purposes, the manufacturer will not be responsible;
- 2) When using an external power supply, make sure that the voltage is within the voltage range indicated on the AC adapter, otherwise it may cause injury to the operator or patient;
- 3) The AC adapter plug is a segmented instrument for grid power supply, and should not be placed in places where it is difficult to disconnect the instrument.
- 4) The use of the instrument is restricted to specialized dentists in hospitals or dental clinics;
- 5) The use of non-original accessories, especially with other gutta percha injecting needles/AC adapter may be dangerous to the patient or operator, as well as causing damage to the instrument;
- 6) Gutta percha injecting needles and thermal protector cap are not factory sterilized and should be cleaned, disinfected and sterilized in strict accordance with the requirements of Chapter 9 before use for therapeutic purposes.
- 7) Do not install, remove or replace the gutta percha injecting needle while it is heated;
- 8) Do not pre-bending the gutta percha injecting needle with a device other than the matching wrench;
- 9) Do not use excessive force when pre-bending the gutta percha injecting needle to prevent it from breaking. When the needle is bent or worn out, it will cause a deterioration of the gutta-percha guiding ability, and the operator should replace the gutta percha injecting needle with a new one according to the clinical conditions;
- 10) Before use, please make sure the gutta percha injecting needle is installed in place to prevent it from falling off or overflowing gutta-percha during use;
- 11) Check the instrument before use to make sure there are no abnormalities before use;

Guidance & Declaration - Electromagnetic immunity			
The model C-FILL is intended for use in the electromagnetic environment specified below. The customer or the user of the model C-FILL should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the model C-FILL MINI, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.  <b>Recommended separation distance</b> $d = [3,5/V] \times \sqrt{P}$ $d = 1.2 \times \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \times \sqrt{P}$ 800 MHz to 2.7 GHz  where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).  Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, <sup>a</sup> should be less than the compliance level in each frequency range. <sup>b</sup>  Interference may occur in the vicinity of equipment marked with the following symbol:  
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz  385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2: 2014+A1:2020)	10 V/m 80 MHz to 2.7 GHz  385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2: 2014+A1:2020)	
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.			
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the model C-FILL is used exceeds the applicable RF compliance level above, the model C-FILL should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the model C-FILL.			
b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.			

Guidance & Declaration – electromagnetic immunity			
The model C-FILL is intended for use in the electromagnetic environment specified below. The customer or the user of the model C-FILL should assure that it is used in such an environment.			
Immunity test	IEC 60601 Test Levels	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV, ±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±6 kV, ±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/ burst IEC 61000-4-4	±2kV for power supply lines ±1 kV for Input/output lines	±2kV for power supply lines	Mains power quality should be that of a typical commercial or Hospital environment.
Surge IEC 61000-4-5	±0.5 kV, ±1 kV line to line ±0.5 kV, ±1 kV, ±2 kV line to ground	±0.5 kV, ±1 kV line to line	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % $U_T$ (>95% dip in $U_T$ ) for 0.5 cycle <5 % $U_T$ (>95% dip in $U_T$ ) for 1 cycle 40% $U_T$ (60% dip in $U_T$ ) for 5 cycles 70% $U_T$ (30% dip in $U_T$ ) for 25/30 cycles <5% $U_T$ (>95 % dip in $U_T$ ) for 5 sec	<5 % $U_T$ (>95% dip in $U_T$ ) for 0.5 cycle <5 % $U_T$ (>95% dip in $U_T$ ) for 1 cycle 40% $U_T$ (60% dip in $U_T$ ) for 5 cycles 70% $U_T$ (30% dip in $U_T$ ) for 25/30 cycles <5% $U_T$ (>95 % dip in $U_T$ ) for 5 sec	Mains power quality should be that of a typical commercial or Hospital environment. If the user of the model C-FILL requires continued operation during power mains interruptions, it is recommended that the model C-FILL be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE:  $U_T$  is the a.c. mains voltage prior to application of the test level.

- 12) When using the instrument, please do not touch the front heat generating part of the instrument and the gutta percha injecting needle, and be sure to install the thermal protector cap before use to avoid scalding the user or the patient;
- 13) The temperature of the gutta percha injecting needle exceeds 100°C after heating, so that it must not be left in the root canal for more than 5 seconds at a time;
- 14) Turn off the power immediately after the instrument has been used;
- 15) To avoid electric shock, do not insert other objects into the instrument. This may cause electric shock or damage the instrument;
- 16) Avoid liquids entering the instrument during cleaning to avoid short circuits and malfunctions;
- 17) In the event of serious abnormalities in the instrument caused by improper use or physical damage, stop using and turn off the instrument immediately.
- 18) Modification of this instrument is strictly prohibited. If repairs are required, only the manufacturer and authorized dealers may open the instrument;
- 19) The instrument generates electromagnetic interference, do not use it around patients with cardiac pacemakers or in the vicinity of electronic surgeries;
- 20) Unstable voltages and in electromagnetic fields can interfere with the proper operation of the instrument;
- 21) Incorrect replacement of lithium batteries causes unacceptable risks, and untrained personnel causes hazards (source) (such as overtemperature, fire or explosion).

## 2 Intended use

The device is intended for injection of Gutta-percha into a prepared root canal for obturation.

It is intended exclusively for use by licensed dentists and endodontists only.

## 3 Contraindications

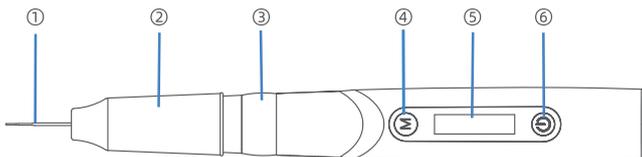
Do not use this instrument on patients with implanted pacemakers or other systems.

## 4 List of accessories

Obturation Handle	1	Wrench	1
Charging Base	1	Cleaning Brush	1
AC adapter	1	Thermal protector cap	2
Gutta percha injecting needle	2(25 Ga) 2(23 Ga)	Test gutta-percha	1
User Manual	1		

## 5 Product Description

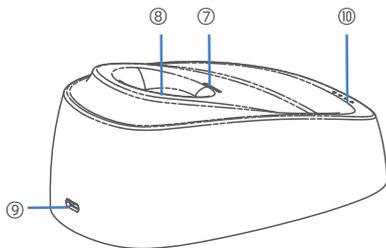
### Obturation Handle



- ① Gutta percha injecting needle
- ② Thermal protector cap
- ③ Heating/injection button(360°button)
- ④ Mode button
- ⑤ Display
- ⑥ On/Off button

### Charging Base

- ⑦ Handle charging indicator
- ⑧ Handle charging contact
- ⑨ AC adapter jack
- ⑩ Base charging indicator



## 16 EMC

This product needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided, and this instrument can be affected by portable and mobile RF communications equipment.

### Warning:

- Do not use a mobile phone or other instruments that emit electromagnetic fields, near the instrument. This may result in incorrect operation of the instrument.
- This instrument has been thoroughly tested and inspected to assure proper performance and operation!
- This instrument should not be used adjacent to or stacked with other instrument and that if adjacent or stacked use is necessary, this instrument should be observed to verify normal operation in the configuration in which it will be used.

serial number	name	Cable length (m)	Shielded wire	Remarks
1	AC Adapter Cable	1.5	No	

### Guidance and Manufacture's Declaration - Electromagnetic Emission

The model C-FILL is intended for use in the electromagnetic environment specified below. The customer or the user of the model C-FILL should assure that it is used in such an environment. this electromagnetic environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The model C-FILL uses RF energy only for their internal function. Therefore, their RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR11	Class B	The model C-FILL is suitable for used in domestic establishment and in establishment directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

## 15 Symbols

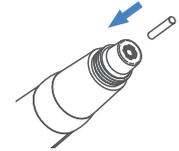
	Note		warning
	Refer to instruction manual		Sterilizable in a steam sterilizer (autoclave) at the temperature specified
	Keep dry		Fragile, handle with care
	Vertical up		Used indoor only
	Serial number		Class II equipment
	Alternating current		Direct current
	Type B applied part		Special disposal of waste electrical and electronic equipment
	Mode button		On/Off button
	Manufacturer		Date of manufacture
	Medical device		Caution
	Heating		Holding temperature
	Speed icon—slow		Speed icon—fast
	Heating failed		

## 6 Installation and use

### 6.1 Installation and disassembly

#### 6.1.1 Installation of gutta-percha

Select a gutta-percha that is the right size for the instrument and fit the gutta-percha completely into the heating chamber.



#### Warning:

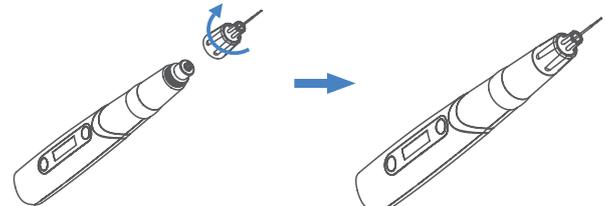
- Please purchase certified (e.g. CE or FDA approved) gutta-percha, poor quality gutta-percha may cause incomplete heating leading to clogging of the syringe;
- It is recommended to use gutta-percha with a diameter of less than 3mm and a length of less than 17mm;
- Only insert one gutta-percha at a time, the melting point must be below 200°C;
- Gutta-percha not fully pushed into the heating chamber can cause clogging when used.

#### 6.1.2 Installation of Gutta percha injecting needle

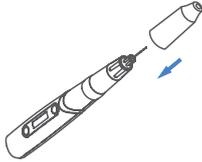
- 1) Select the appropriate gutta percha injecting needle according to the root canal and tighten the gutta percha injecting needle to the handle in a clockwise direction.

Type	Sizes
23Ga	Length: 20±1mm, Inner Diameter: 0.4±0.05mm, Outer Diameter: 0.65±0.05mm
25Ga	Length: 20±1mm, Inner Diameter: 0.3±0.05mm, Outer Diameter: 0.5±0.05mm

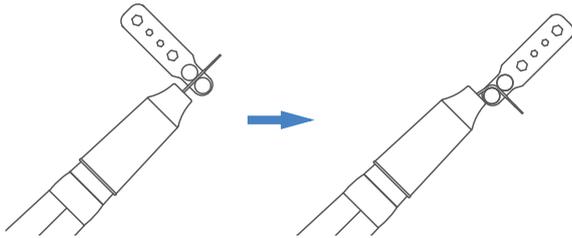
- 2) Make sure the gutta percha injecting needle is in place to prevent it from falling off or overflowing gutta-percha during use.



### 6.1.3 Installation of Thermal protector cap

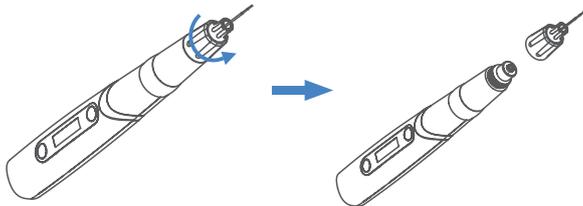


### 6.1.4 Pre-bending of the gutta percha injecting needle



### 6.1.5 disassembly of Gutta percha injecting needle

Turn off power, wait 5min to cool down and remove the thermal protector cap, then rotate the Gutta percha injecting needle in the counterclockwise direction to remove it.



## 12 Guarantee

- 1) This instrument does not contain self-repair spare parts, machine maintenance should be designated by the manufacturer of professional personnel.
- 2) The Obturation Handle and Charging Base are guaranteed for 12 months from the date of purchase, and the accessories of the product are guaranteed for 6 months. Damaged or used up, they can be purchased from our company.
- 3) The guarantee is valid for normal usage conditions. Any modification or accidental damage will render the guarantee void.

## 13 Disposal of Medical Instruments

The device and its packaging are designed to be as environmentally friendly as possible.



In accordance with the principles, standards and requirement of the country (region) in which you are located, dispose of the old electrical equipment. Ensure that pollution is not produced in the process of waste disposal.

## 14 Technical Specifications

- 1) AC adapter: Input: 100-240V ~ 50/60Hz  
Output: 5V  4A
- 2) Input power: 30VA
- 3) Obturation Handle battery: d.c. 3.6V 2000mAh  
Charging Base battery: d.c. 3.6V 3000mAh
- 4) Temperature: 140 °C, 160 °C, 180 °C, 200 °C
- 5) Degree of Protection against Electric Shock: Type B applied part
- 6) Duty cycle: Max.T\_ON: 1min, Min.T\_OFF: 3min
- 7) Degree of Protection (IEC 60529): IPX1
- 8) Applied Part: Gutta percha injecting needle
- 9) Gutta percha injecting needle material: PEEK, Ag, 304 stainless steel
- 10) Overvoltage category: Class II
- 11) Pollution degree: Degree 2

down then remove it;

- The above methods cannot solve the problem, connect the manufacturer or authorized dealers.

#### 4) Severe overflow of gutta-percha

- Temperature is too high and does not match the melting point of the gutta-percha. Please set lower temperature that matches the melting point;
- The above methods cannot solve the problem, connect the manufacturer or authorized dealers.

#### 5) Display



- Heating failed, connect the manufacturer or authorized dealers.

#### 6) When using, the instrument does not push the gutta-percha

- The internal pusher is returning. Please wait for it to return completely.
- The above methods cannot solve the problem, connect the manufacturer or authorized dealers.

#### 7) The internal pusher can not return/can not put in gutta-percha

- The internal pusher is stuck, connect the manufacturer or authorized dealers.

## 11 Operating, Transport and Storage Environment

### Operating environment :

operating temperature	+5°C - +40°C
Operating humidity	20% - 80%
atmospheric pressure	80kPa - 106kPa

### Transport and Storage environment :

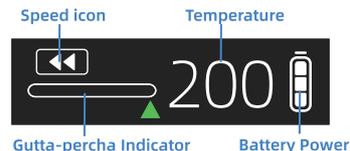
Storage temperature	-10°C - +55°C
Storage humidity	≤93%
atmospheric pressure	50kPa - 106kPa

## 6.2 Operating

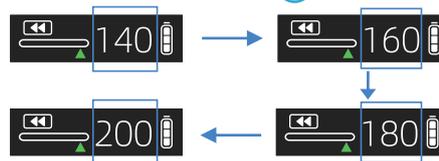
### 6.2.1 Power

Long press  to turn the instrument on/off.

### 6.2.2 Adjustment of temperature and speed



1) To adjust the temperature, short press  to switch temperature:



### Warning:

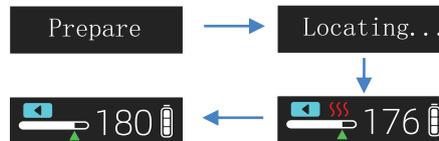
The proper heating temperature should be selected according to the melting point of the gutta-percha. Too low a temperature will result in incomplete melting of the gutta-percha, while too high a temperature will result in overheating of the gutta-percha causing serious overflow.

2) To adjust the speed, long press  to switch slow/fast:



### 6.2.3 Heating

1) Short press the 360° button to start heating and locating, when heating the 360° button light flashes and the display:



### Note

1. When the set temperature is displayed and the 360° button light is constantly on indicates that the heating is complete;
  2.  White bar: actual amount of gutta-percha after locating.
  3. During the heating, short press  can stop heating.
- 2) If the heating is completed within 1min user no operation, the device will automatically holding temperature 3min (70 °C), short press 360° button or  button to restore the set temperature.

### Note

When holding temperature the display is:



- 3) The instrument enters hibernation after 3min of holding temperature, the instrument can be woken up by pick up it within 30min of hibernation, and the instrument will be shut down automatically after 30min.

#### 6.2.4 Injection of gutta-percha

- 1) Long press the 360° button to inject the gutta-percha (release the button to stop inject). During the inject, the buzzer beeps, the speed icon  flashes, and the gutta-percha indicator gradually becomes empty:



### Note

The instrument is equipped with automatic locate function. Due to the principle of thermal expansion and contraction, it will be a little overflow of gutta-percha after heating, selecting the temperature that matches the melting point of the gutta-percha to heat will reduce overflow .

- 2) When the gutta-percha is completely consumed, the buzzer will sound a long beep at this time. The internal pusher will automatically return and the display is  ;

When the display is  and the buzzer beeps twice, the internal pusher return complete. You can short press any button to return to the standby interface. Wait 5min for the temperature of the instrument to decrease and then you can place a new gutta-percha.

## 9.5 Packaging

Put the gutta percha injecting needle and thermal protector cap into the sterilized bag conforming to ISO 11607-1 standard for sealing.

## 9.6 Sterilization

Use an autoclave in accordance with EN 13060 for sterilization. Sterilize in an autoclave according to ISO 17665-1.

- 1) Sterilization parts: gutta percha injecting needle, thermal protector cap.
- 2) Sterilization method: autoclave.
- 3) Sterilization conditions: 210kPa, 134°C for not less than 5 minutes.

### Warning:

- The gutta percha injecting needle and thermal protector cap should be cleaned, disinfected and sterilized before first use and after each use.
- If the sterilization bag is found to be broken before use, the gutta percha injecting needle and thermal protector cap should be cleaned, disinfected and sterilized again.
- Only the gutta percha injecting needle and thermal protector cap can be autoclaved, and other parts cannot be autoclaved.

## 9.7 Storage

Store sterilized instruments in a dry, clean, dust-free environment until next use.

## 10 Troubleshooting

### 1) Cannot turn on the power

- The battery is low, please charge in time;
- Battery failure, connect the manufacturer or authorized dealers.

### 2) No gutta-percha flow out

- Check if the gutta-percha has been used up, place a new one;
- Check if the Gutta percha injecting needle is damaged or plugged, replace the new one;
- Neither of these two questions, connect the manufacturer or authorized dealers.

### 3) Cannot remove the Gutta percha injecting needle

- Turn on the instrument, start the clean program, wait the instrument to cool

## 9 Cleaning, disinfection and sterilization

### Caution:

Cleaning, disinfection, and sterilization have limited impact on the reusable parts of the instrument. Therefore, the number of times the procedure is repeated is determined by the degree of wear of the part. If visual inspection reveals damaged parts, stop using them and purchase new parts from the manufacturer or dealer.

### 9.1 Pre-processing

- 1) Refer to 6.2.5 start the clean program to discharge the remaining gutta-percha;
- 2) Shut down the instrument, wait for 5min to let the instrument cool down, remove the thermal protector cap and gutta percha injecting needle into the stainless steel basin.

### Warning:

Do not remove the Thermal protector cap and Gutta percha injecting needle immediately after use, wait the instrument cools down before operation.

### 9.2 Cleaning

- 1) Use medical tweezers to clean out any residual gutta-percha from the gutta percha injecting needle;
- 2) Use a cleaning brush to clean the remaining gutta-percha inside of the heating chamber;
- 3) Rinse the gutta percha injecting needle, thermal protector cap, Wrench and cleaning brush under running water (<40°C), then remove any visible dirt from the surface with a wet cloth.

### 9.3 Disinfection

Disinfect all surfaces of the instrument and its components by wiping them with a small amount of 75% alcohol on gauze.

### 9.4 Inspection

After cleaning, check the disinfected instrument and components no visible dirt are considered to be clean. If the gutta percha injecting needle has corrosion and rust should be immediately discontinued.

### Warning:

- Please check the instrument before use, any abnormality please do not use it and contact the manufacturer or local distributor;
- Please make sure that the thermal protector cap is installed before use to avoid scalding the patient;
- During use, the user should avoid touching the hot part of the instrument and the gutta percha injecting needle, and should not allow the gutta percha injecting needle to contact the patient's oral soft tissues;
- Continuous operation time should not exceed 1 minute, if you want to continue to use, you need to turn off and wait for at least 3 minutes.
- If you want to put in another gutta-percha, refer to "6.2.5 Replace the gutta-percha".

### 6.2.5 Replace the gutta-percha

- 1) There is residual gutta-percha in instrument: long press  and  to start the clean program so that the remaining gutta-percha is automatically discharged and the internal pusher is automatically return, at this time the display is:

Push GP  
& return...

When the display is  and the buzzer beeps twice, it means that the clean program completed. At this time, short press any button to return to the standby interface.

- 2) Turn off the instrument, wait for 5min for the gutta percha injecting needle to cool down before removing it, and then use a cloth moistened with alcohol to wipe away the excess gutta-percha, followed by putting in new gutta-percha.

### Warning:

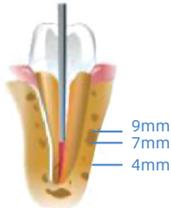
Wait for the alcohol to completely evaporate before put in new gutta-percha. Unevaporated alcohol can be dangerous when heated at high temperatures.

### Note

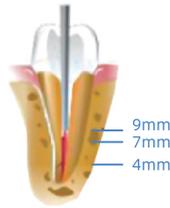
If there is no remaining gutta-percha in instrument, can simply perform step 2) to place the new gutta-percha.

## 7 Clinical use

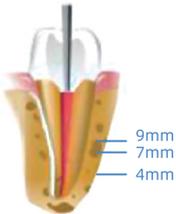
- 1) For filling 2/3 of the root canal. Heat 3-5 seconds when the needle is in contact with the surface of the already filled gutta-percha;



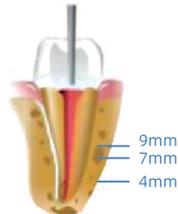
- 2) Injecting gutta-percha 1-2 mm, exit the root canal. Then press gutta-percha tightly;



- 3) Lifting up the needle while squeeze the melted gutta-percha into the root canal. Then press gutta-percha tightly;



- 4) Filling entire root canal completely.



## 8 Charging

### Battery charging:

Method 1: Use the AC adapter to charge the Obturation Handle and Charging Base at the same time.

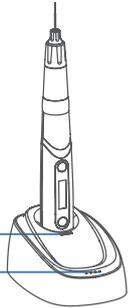
Method 2: Use the Charging Base to charge the Obturation Handle. Simply place the handle on the Base.

### Charging indication:

- 1) During charging: the Base charging indicator is flashing in blue, and the Handle charging indicator is flashing in orange.
- 2) Fully charged: the Base charging indicator is fully illuminated in blue, and the Handle charging indicator is fully illuminated in green.

Handle charging indicator

Base charging indicator



### Note

When use Method 2, the Base charging indicator indicates the battery power of the Base.

### Warning:

- When the battery power icon flashes and the buzzer beeps, it means that the instrument is in a low voltage and it will soon shut down;
- Please use the original AC adapter, otherwise it will cause short circuit and damage the instrument;
- Please use the original Charging Base for charging;
- Do not use the instrument when charging;
- When charging, if the Base charging indicator neither flashes nor lights up constantly, the AC adapter is not connected correctly, please recheck it;
- When the instrument is fully charged, disconnect the AC adapter from the power source and unplug the AC adapter;
- Please charge the instrument in time when the power is low;
- When the instrument is not used for a long time, it should be charged once a month at least;
- Users should not replace the battery without authorization, if the battery is damaged, please contact the manufacturer and dealers.