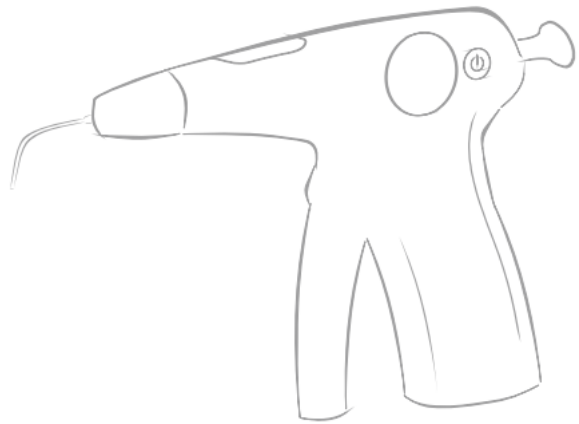
Endodontic Obturation Systems

User Manual

C-FILL

mini G



COXO

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Introductions

Thank you for purchasing the device.

For optimum safety and performance, read this manual thoroughly before using this device and pay close attention to warnings and cautions.

Keep this manual in a handy place for quick and easy reference.

Recommended separation distances between portable and mobile RF communications equipment and the device

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as 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**		
	150 kHz to 80 MHz $d=1.2xP^{1/2}$	80 MHz to 800 MHz $d=1.2xP^{1/2}$	800 MHz to 2.5 GHz $d=2.3xP^{1/2}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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

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

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

Guidance and Manufacture's Declaration – Electromagnetic Immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of device 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 6 Vrms in ISM bands 3 V/m 80 MHz to 2.7 GHz	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM bands 3 V/m 80 MHz to 2.7 GHz	Portable and mobile RF communications equipment should be used no closer to any part of the instrument, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended Separation Distance $d=1.2xP^{1/2}$ $d=1.2xP^{1/2}$ 80 MHz to 800 MHz $d=2.3xP^{1/2}$ 800 MHz to 2,5 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,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC 61000-4-3	385MHz- 5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014)	385MHz- 5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014)	
NOTE 1: At 80 MHzand 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 device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device. b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Table of Contents

Warning

1. Improper usage of this device may cause injury to patients, operators and dental assistants, and/or damage to the product. It is intended exclusively for use by licensed dentists and endodontists only.
2. Needles are very hot when device is activated, thus care must be taken by the dentist, assistant and patient not to contact the Needle while hot. Usage of a rubber dam is strongly recommended for proper isolation of the tooth.
3. To reduce the risk of burn when changing the Needle, make sure the device has been off for a minimum of five minutes and the front part is cool to the touch before changing the Needle.
4. The temperature of the Needle can reach 230℃; therefore, it should not be used inside the root canal for more than 5 seconds at a time.
5. Do not use any other Needles except the ones supplied by our company. Use of any Needles, adapter or battery that is not supplied by our company may result in electrical shock, fire, or explosion and void Warranty.
6. Please confirm that the power supply is AC 100-240V before charging, otherwise the device will be damaged.
7. Place the device in a location where it is easy to disconnect the power.
8. Do not insert other objects into the device , or will result in electric shock or device damage.
9. Avoid the liquid entering the device to avoid short circuits and faults.
10. Do not dismantle the device by yourself. If you need to repair the device, please contact the service center.
11. After the device is turned off, it needs to be cooled for 5 minutes before it can be stored.
12. It is recommended that battery be fully charged before using the device for the first time.
13. Do not autoclave the Obturation Gun or Charging Base.

Guidance and Manufacture's Declaration – Electromagnetic Immunity

The device is intended for use in the electromagnetic environment specified below. The customer or the user of device should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±4 kV, ±8kV, ±15 kV air	±8 kV contact ±4 kV, ±8kV, ±15 kV air	Floors should be wood, concrete or ceramic tile. If floor 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 ±1 kV for Input/output lines	Mains power quality should be that of atypical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5 kV & ±1 kV differential mode ±0.5 kV, ±1 kV & ±2kV common mode	±0.5 kV & ±1 kV differential mode ±0.5 kV, ±1 kV & ±2kV common mode	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	100 % U_T (100% dip inU_T.) for 0.5 cycle 100 % U_T (100% dip inU_T.) for 1 cycle 30 % U_T (70% dip in U_T) for25/30 cycles 100 % U_T (100% dip inU_T.) for 250/300 cycle	100 % U_T (100% dip inU_T.) for 0.5 cycle 100 % U_T (100% dip inU_T.) for 1 cycle 30 % U_T (70% dip in U_T)for 25/30 cycles 100 %U_T (100% dip inU_T.) for 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from a unit eruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3A/m	3A/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.

Guidelines and Manufacturer's Declaration-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 device can be affected by portable and mobile RF communications equipment.

⚠ **Caution:**

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

Guidance and Manufacture's Declaration – Electromagnetic Emission		
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic Environment – Guidance**
RF emissions CISPR 11	Group 1	The device use RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Class B	The device is suitable for use in all establishments, including domestic establishments directly connected to the public low-voltage power supply network with specific requirement.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Intended Used

The device is intended for injection of Gutta into a prepared root canal for obturation. It is intended exclusively for use by licensed dentists and endodontists only. A dental dam should be used with any dental procedure!

Contraindications

1. Do not use the device on patients with pacemakers.
2. Do not use disinfectants that contain Bleach or Ammonium Chloride to clean the device.

Features

1. Package contents

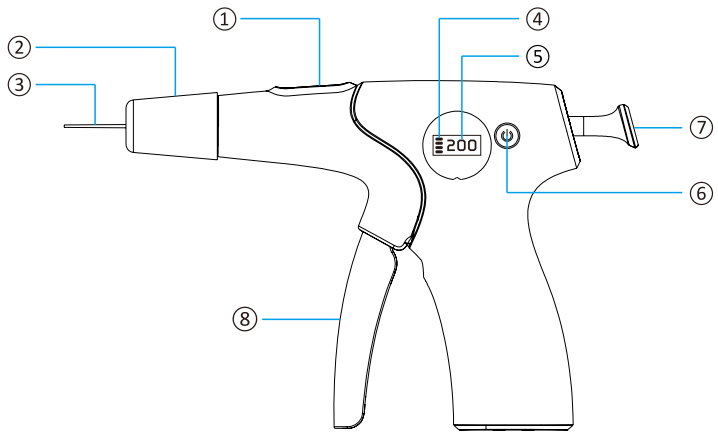
• Obturation Gun	1	• Prevent Overflow Rings	10
• Charging Base	1	• Plunger	1
• Adapter	1	• Needles (One-time use)	4
• Thermal Protectors Cap	2	• Needles Bender	1
• Cleaning Brush	1	• User Manual	1

2. Technical Data

- Adapter Input: AC 100 - 240V 50/60Hz
- Adapter Output: DC 5V, 1.5A
- Battery: Rechargeable Li-ion battery (DC3.7V, 2000mAh)
- Classification of Protection against Electric Shock: Class II equipment
- Degree of Protection against Electric Shock: Type B equipment

Product Description

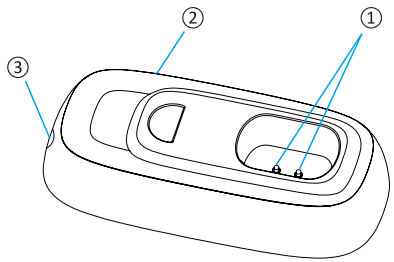
Obturation Gun



① Pellet Loading Slot
② Thermal Protectors Cap
③ Needle
④ Battery Indicator
⑤ Temperature Display
⑥ Power Switch
⑦ Plunger
⑧ Trigger

Charging Base

① Charging Contact Terminals
② Charging Status Indicator
③ Power Adapter Jack



Standard Symbols

Warning	Caution	Refer to Instruction Manual/Booklet
Class II Equipment	Type B Applied Part	Direct Current
Authorized Representative	Serial Number	Alternating Current
Manufacturer	CE marked product	WEEE Directive Marking
Fragile	Keep Dry	This Way Up

Operation and Storage Environment

Operation Environment	
Temperature	5℃ to 40℃
Humidity	20%RH to 80%RH
Atmospheric Pressure	86kPa to 106kPa

Storage Environment	
Temperature	-10℃ to 55℃
Humidity	Less than 93%RH
Atmospheric Pressure	50kPa to 106kPa

Recycling and Disposal

The device and its packaging are as environmentally friendly as possible.
Disposal of device

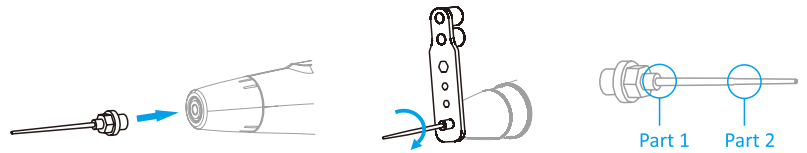
In accordance with the principles, standards and requirement of the country (region) in which you are located, dispose of the old electrical device. Ensure that pollution is not produced in the process of waste disposal.

Warranty

Product and technical service are in charge of our company, the technical department will provide technical support when technical problems arise. The Obturation Gun and Chasing Base are guaranteed for 2 years. The battery and adapter are guaranteed for 6 months. Other accessories are not included in the guarantee.

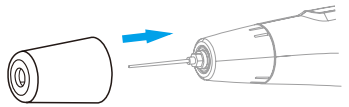
Installation

1. Install the Needle

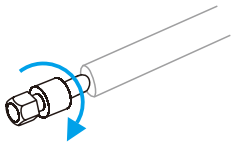


Note:
- *Do not over tighten the Needle.*
- *Use Needle Bender to bend Needle as desired.*
- *As shown in the figure, parts 1 and 2 of the Needle cannot be bent.*

2. Install the Thermal Protectors Cap

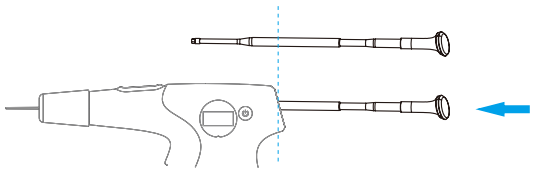


3. Install the Prevent Overflow Rings



Caution:
- The Prevent Overflow Ring is consumable parts, which damaged would cause blocking or backflow. Always check whether it is intact.
- Do not over-tighten!

4. Install the Plunger



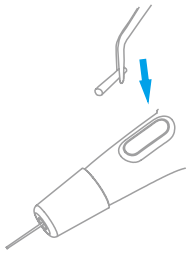
Instructions for Use

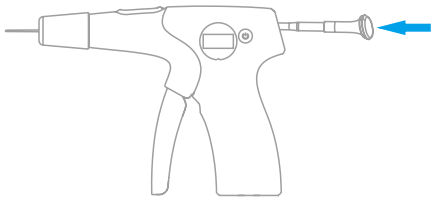
Warning:

When handling the Obturation Gun, do not touch the front tip area of the Gun as it is extremely hot. Always use the protective cover to prevent burning user or patient.

1. Insert the Gutta-Percha

To insert the Gutta-Percha into the Pellet Loading Slot, pull the Plunger back (but not out of the Gun) to clear the loading slot. Tilt the front of Gun down and place the Gutta-Percha inside the loading slot, then use the Plunger to push the Gutta-Percha forward until it enters the heating chamber.





Caution:

- Gutta-Percha from other manufacturers may not be the proper size or may require different melting temperatures.
- Only insert one Gutta-Percha at a time.
- Failure to fully insert the Plunger will result in the trigger-advance mechanism not operating properly.

2. Turn Power On/Off

Hold down the Power Switch to turn power on/off.

Troubleshooting

1. Device does not power on when Power Switch is pressed.

a. Check that the battery is charged. Recharge as needed.
b. If the battery cannot be recharged, a new battery may be ordered from your local dealer.

2. Material does not flow from the needle.

a. The Plunger it is fully advanced. Pull it back and insert a new Gutta-Percha into the Pellet Loading Slot.
b. Check the Prevent Overflow Rings. If worn or damaged, replace a new one.
c. Replace the Needle.

3. Power turns off.

It is normal for the power to turn off automatically after 15 minutes of non-use to conserve the battery. Hold down the Power Switch to turn power on.

4. The Plunger cannot be retracted.

If the Plunger cannot be retracted, it is most likely due to cooling and firming of material in the chamber with the Plunger left in. To remove Plunger, turn on the Gun and set temperature at 200 ℃. Wait for Gun to reach selected temperature and then retract the Plunger.

5. The error code 'oPn' is displayed on the screen

If this error code is displayed on the screen, please contact authorized dealer's customer service department.

b. Automatic drying: Perform automated dry cycle for 15 minutes at (40 -55) ℃.

7. Inspection and Maintenance

After cleaning and disinfection, visually inspect the Thermal Protector Cap and the Plunger. If no visible contaminants are found, it means that the Thermal Protector Cap and the Plunger has been cleaned. If it is found that the Plunger is corroded and rusted, stop using it immediately.

8. Package

Immediately after drying, put the Thermal Protector Cap and the Plunger into a steam sterilization bag for sealed packaging.

⚠ **Caution:**

Steam sterilization bag should comply with ISO 11607-1 and must be sealed with a sealing machine.

9. Sterilization

Use an autoclave in accordance with EN 13060 for sterilization.
Sterilize in an autoclave according to ISO 17665-1.
a. Sterilization parts: Thermal Protector Cap, Plunger
b. Sterilization method: Autoclave
c. Sterilization conditions: 134 ℃for not less than 5 minutes

⚠ **Caution:**

Only the Thermal Protector Cap and the Plunger can be autoclaved, and other parts cannot be autoclaved.

10. Storage

Store the sterilizing equipment in a dry, clean and dust-free environment at a suitable temperature of 5℃to 40 ℃.

3. Temperature Control

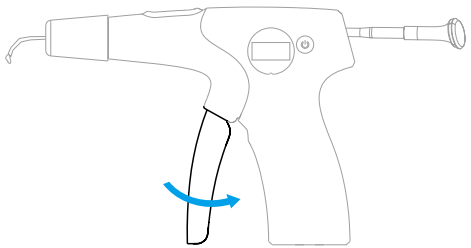
To change the desired temperature, continue pressing the Power Switch until the desired temperature is displayed.

⚠ **Caution:**

- After selecting the desired temperature, the temperature display will begin to show the actual temperature which will continue to change until it reaches the desired temperature.
- The Needle is very hot when device is activated, thus care must be taken by the dentist, assistant and patient not to contact the Needle while hot.
- The temperature display will show the temperature inside the pellet chamber within ±10℃.

4. Pump the Trigger

Pump the trigger to further advance the Plunger until a small amount of material extrudes from the Needle tip.



⚠ **Caution:**

- Do not pump the trigger when the device does not reach the desired temperature.
- Load another Gutta-Percha only once the Gun has time to cool and when all material from the previous Gutta-Percha has been extruded through the Needle.
- When the Prevent Overflow Ring is damaged, replace it in time.

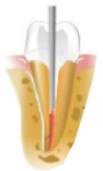
Clinical Use

1. Needle insertion

Insert the Needle as far as it will go into the canal space without binding.

2. Soften

Wait 5 seconds until the surface of filled Gutta-Percha soften.



3. Injection

Pump the trigger and fill the Gutta-Percha up to root canal. The Needle would be push by filled Gutta-Percha naturally.

4. Soften

Compact Gutta-Percha with big plugger.

Warning

After manual cleaning, heat disinfection or sterilization must be carried out in accordance with EN 13060.

5. Automatic Cleaning and Disinfection

Put the Thermal Protector Cap and the Plunger on the try of the washer-disinfector and select "surgical instrument" to start the automatic cleaning and disinfection procedure.

Automatic disinfection procedures:

a. Pre-cleaning: pre-wash for 4 minutes with tap water (<40℃).
b. Washing stage: soaking and cleaning with a multi-enzyme cleaning agent at 55℃ for 6 minutes.
c. Rinse stage I: rinse with tap water (<40 ℃) for 1 minute.
d. Rinsing stage II: flushing with tap water (<40 ℃) for 1 minute.
e. Disinfect (washing) for 10 minutes in hot water (90 ℃).
f. Rinse for 5 minutes in hot water (70 ℃).
g. Perform automated dry cycle for 15 minutes at (40-55)℃.

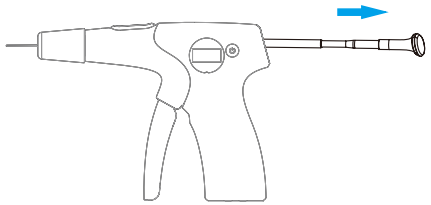
Caution:

- The user must follow the special instructions of the manufacturer of the fully automatic washing machine. In order to ensure the cleaning and disinfection effect, the cleaning and disinfection time should not be less than the time recommended by the manufacturer.
- We recommend the use of proven HIP™ Ultra cleaning solution or cleaning solution that complies with local regulations (e.g. CE, FDA approval).
- Please use a washer-disinfector that meets the requirements of ISO 15883.
- Considering that some countries have different requirements for A0 values, please refer to ISO 15883 for temperature and time of disinfection.

6. Drying

a. Manual drying: Dry the Thermal Protector Cap and the Plunger with a lint-free cotton cloth. The Thermal Protector Cap can be dried using sterile compressed air (1-2 Bar).

Pull out the Plunger



b. Flush the Thermal Protector Cap and the Plunger with running tap water (<40 ℃) until all visible residue is removed.

3. Manual Cleaning

a. Flush the Thermal Protector Cap and Plunger in running tap water (<40 ℃) respectively. Use a soft brush to remove the visible soil on the screw joint at the front of the Plunger.
b. Put the Thermal Protector Cap and Plunger into the multi-enzyme cleaning agent for 10 minutes to decompose soils. Follow the instructions of the cleaning agent manufacturer.
c. Immerse the Thermal Protector Cap and the Plunger under running tap water for at least 1 minute to remove the residue of the cleaning agent.

⚠ **Caution:**

We recommend the use of proven 3M Multi-enzyme Cleaner or multi-enzyme cleaning solution that complies with local regulations (e.g. CE, FDA approval).

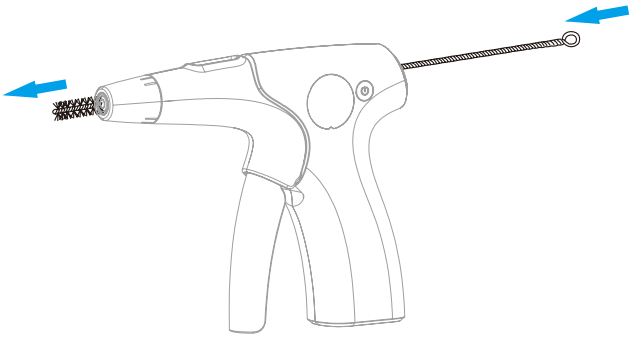
4. Manual Disinfection

a. Put the Thermal Protector Cap and the Plunger into the dish containing Disinfection Alcohol and soak for 10 minutes for immersion disinfection.
b. Rinse the Thermal Protector Cap and the Plunger under running tap water for at least 1 minute to remove the residual disinfectant.

Maintenance

Surfaces of the Gun can be cleaned with soft towel and a mild detergent or rubbing alcohol.

To remove remaining material from inside the Pellet Loading Slot, set the temperature to 200℃, express any remaining material and then turn off the Gun. Insert Cleaning Brush through the back of the Gun, and then pull it out through the front part of the Gun.

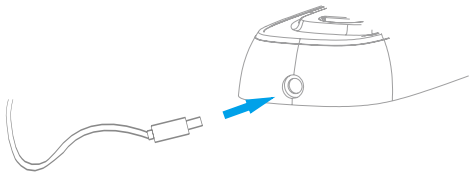


⚠ **Caution:**

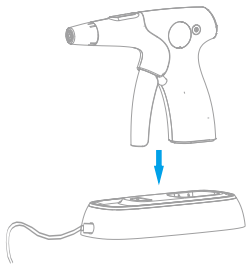
- Do not put any cleaner or chemicals on the cleaning brush before inserting it into the chamber.
- After use, the Cleaning Brush should be rinsed off immediately with running tap water and soaked with alcohol.
- Do not autoclave the Cleaning Brush!

Charging the Battery

1. Connect the Power Adapter to the Charging Base.



2. Position the Obturation Gun on the Charging Base correctly.



3. If the correct connection is made, the LED charging status will display an orange light during charging. Once the battery is fully charged, the LED charging status indicator will turn green.

⚠ **Caution:**

- If the display window shows 'Er1', this indicates that the device is in low voltage, there will be an alarm prompt, and the device will automatically shut down after 5 seconds.
- If the LED is neither orange nor green, the charging terminals are not properly connected. Re-align the Obturation Gun on the Charging Base and also check that you are getting power to the Charging Base.
- Needle should be removed while charging. Please keep the Needle disconnected from the Obturation Gun after each treatment.
- If the device has not been in use for more than a month, it may not function correctly due to natural discharge of the battery. Monthly recharging is recommended even when the device has been fully charged but is not in use.

Cleaning, Disinfection and Sterilization

⚠ **Caution:**

Cleaning, disinfection, and sterilization have limited impact on the reusable parts of the device. 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.

1. Preparation for Use

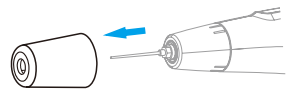
Immediately after use, the reusable parts should be immersed in tap water <40℃ (The quality of drinking water, the 'water' mentioned in this chapter, is required to meet this standard.) to remove dirt. Do not use a fixed detergent or warm water (>40℃), as this will cause the residue to be fixed and affect the post - treatment effect.

Transport to the post - processing area for safe storage to avoid any damage and environmental pollution.

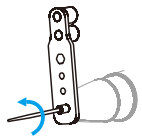
2. Preparation before Cleaning

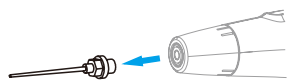
a. Disassemble the reusable parts and place them in a stainless steel box as follows:

Remove the Thermal Protectors Cap



Remove the Needle





Note: 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.