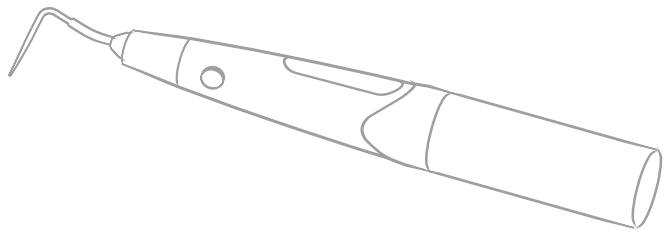
Endodontic Obturation Systems

User Manual

C-Fill Mini P Type



COXO®

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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 $d=1.2 \times P^{1/2}$	80 MHz to 800 MHz $d=1.2 \times P^{1/2}$	800 MHz to 2.5 GHz $d=2.3 \times P^{1/2}$
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.

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.

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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.

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.			

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. Pen Tips are very hot when device is activated, thus care must be taken by the dentist, assistant and patient not to contact the tip while hot. Usage of a rubber dam is strongly recommended for proper isolation of the tooth.
3. The temperature of the Pen Tip can reach 230℃; therefore, it should not be used inside the root canal for more than 5 seconds at a time.
4. Pen Tips must be sterilized before first use and between patient uses. For sterilization of tip, temperature must not exceed more than 134℃ in the autoclave.
5. Do not use any other Pen Tips except the ones supplied by our company. Use of any Pen Tips, 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 Pen or Charging Base.

Intended Used

The device is intended to heat the Pen Tip for warming and softening gutta-percha master cones and searing off gutta-percha cones. 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 Pen 1
- Charging Base 1
- Adapter 1
- Pen Tip 5

  Available Pen Tip Include (Tip Size / Taper):

  XF:#35/02 F: #45/02 FM: #50/04 M: #55/06 ML: #55/08
- User Manual 1

2. Technical Data

- Adapter Input: AC 100 - 240V 50/60Hz
- Adapter Output: DC 5V, 1.5A
- Battery: Rechargeable Li-ion battery (DC 3.7V, 2000mAh)
- Classification of Protection against Electric Shock: Class II equipment
- Degree of Protection against Electric Shock: Type B equipment

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	

Warranty

Product and technical service are in charge of our company, the technical department will provide technical support when technical problems arise. The Obturation Pen 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.

Standard Symbols

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

Product Description

Obturation Pen

① Pen Tip

② Pen Tip Attachment Cap

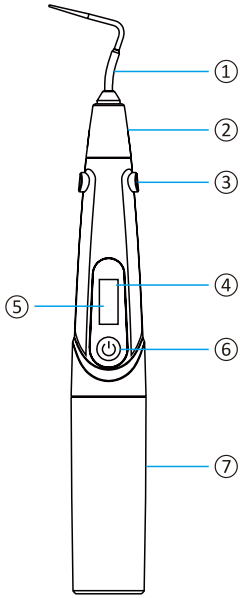
③ Heater Switches

④ Battery Level Indicator

⑤ Temperature Display

⑥ Power Switch/
Temperature Selection Switch

⑦ Battery Casing

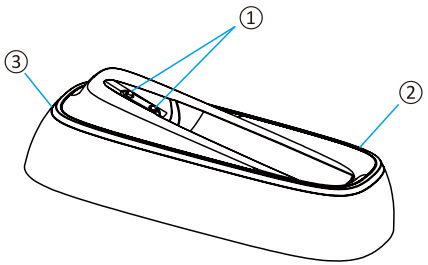


Obturation Pen

① Charging Contact Terminals

② Charging Status Indicator

③ Power Adapter Jack



Installation

1. Install the Battery

a. Insert the Battery into the Obturation Pen as shown in the pictures.

b. Thread the Battery Casing onto the Obturation Pen.

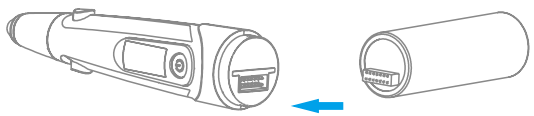
⚠ **Caution:**

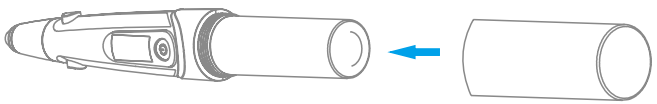
Ensure threads are aligned and avoid excessive forces when threading the Battery Casing onto the Obturation Pen.

c. When replacing the battery, turn the Battery Casing counterclockwise. Separate the Battery from the connector of the Obturation Pen.

⚠ **Caution:**

- When inserting the battery, make sure the connector is properly set.
- Use only battery designed for the device. Other batteries could cause serious damage.
- Do not use a battery if it is leaking, deformed, discolored or if its label is peeled off. It might overheat.
- Do not remove/install the Battery Casing when it is wet.





Troubleshooting

Problem	Cause	Solution
Cannot turn on the power	The battery is low	Please charge in time
The Pen Tip cannot work properly	The pen tip is not reliably connected	Check that the pen tip connection is reliable

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.

b. Sterilization method: Autoclave

c. Sterilization conditions: 134℃ for not less than 5 minutes

⚠ **Caution:**

Only the Pen Tip can be autoclaved, and other parts cannot be autoclaved.

10. Storage

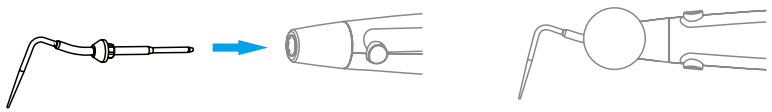
Store the sterilizing equipment in a dry, clean and dust-free environment at a suitable temperature of 5℃ to 40℃.

2. Install the Pen Tip

Insert the Pen Tip into the Obturation Pen as shown in the picture.

⚠ **Caution:**

- Pen Tip is extremely hot during use. Avoid direct contact with the patient's soft tissue in the oral cavity.
- The mouth of the Obturation Pen has 6 different slots for inserting the Pen Tip. Select the appropriate one based on your preferred orientation of the Heater Switches in relation to the Pen Tip.



Instructions for Use

1. Turn Power On/Off

Press the Power Switch to turn power on and hold down it again to turn power off.



⚠ **Caution:**

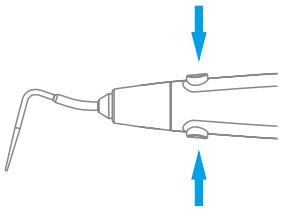
- Hold down the Power Switch to turn power on while set the dominant hand.
- If the display window shows 'oPn', this indicates that the Pen Tip is not connected properly. 

2. Temperature Control

To change the temperature setting, press the Power Switch until reaching the setting you desire: 150 180 200 230

3. Heating the Pen Tip

Hold down either one of the two Heater Switches to heat the Pen Tip.



Caution:

- During normal operation, a beeping noise will indicate that the Pen Tip is hot. Do not touch the Pen Tip until it returns to room temperature.
- To avoid overheating, the device will stop heating automatically after heating over 4 seconds. Release the Heater Switch and hold down it again to continue heating.

Warning:

- Heat activation of the Pen Tip inside the canal should not exceed more than 5 seconds.
- This device shut off automatically if not used for more than 3 minutes. Press the Power "ON/OFF" Switch to turn on the device.
- The Pen Tip is very hot during use. Please perform all endodontic procedures with a rubber dam.
- For safety purposes, place Pen Tip at the orifice of the root canal before activating the Heater Switches. Use caution to avoid contact to the soft tissue of the oral cavity while the Pen Tip is hot.
- When replacing the Pen Tip, turn the power off and ensure the Pen Tip has cooled down sufficiently.
- The Pen Tip should be sterilized prior to use.

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 other 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 Pen Tip with a lint-free cotton cloth.
b. Automatic drying: Perform automated dry cycle for 15 minutes at (40 -55)℃.

7. Inspection and Maintenance

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

8. Package

Immediately after drying, put the Pen Tip 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: Pen Tip

3. Manual Cleaning

Flush the Pen Tip with running tap water (<40℃). Use a soft brush to remove the visible dirt on working part of the pen tip.

⚠ Caution:

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

4. Manual Disinfection

a. Put the Pen Tip into the dish containing Disinfection Alcohol for 10 minutes for immersion disinfection.
b. Rinse the Pen Tip under running tap water for at least 1 minute to remove the residual disinfectant.

⚠ Warning:

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

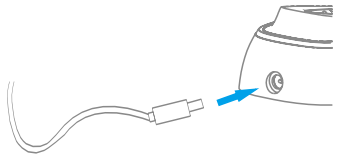
5. Automatic Cleaning and Disinfection

Put the Pen Tip on the tray of the washer-disinfector and select "surgical instrument" to start the automatic cleaning and disinfection procedure.
Automatic disinfection procedures:

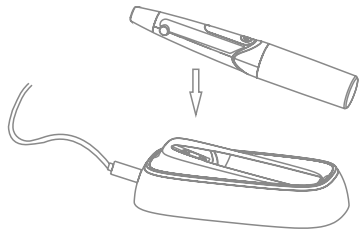
a. Pre-cleaning: pre-wash for 4 minutes with tap water (<40℃)
b. Washing stage: soaking and cleaning with a multi-enzyme cleaning agent at 55℃ for 6 minutes.
c. Rinse stage I: rinse with tap water (<40℃) for 1 minute.
d. Rinsing stage II: flushing with tap water (<40℃) for 1 minute.
e. Disinfect (washing) 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)℃.

Charging the Battery

1. Connect the Power Adapter to the Charging Base.



2. Position the Obturation Pen 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 Pen on the Charging Base and also check that you are getting power to the Charging Base.
- Pen Tip should be removed while charging. Please keep the Pen Tip disconnected from the device 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 commended even when the device has been fully charged but is not in use.

Technique Overview

Step 1: CONE FIT

Select a cone that fits snuggly to Working Length. Trim it 0.5mm from the tip.
Note: Do not use sealer for this step.

Step 2: PLUGGER FIT

Choose the device which most closely matches the taper of the prepared canal. Place the Pen Tip into the canal until it binds.
Note: Pen Tip should be approximately 4 to 7 mm short of Working Length. Move the rubber stop to indicate the maximum depth of penetration.

Step 3: CONDENSE CONE WITH HAND PLUGGER

Coat the cone (fitted in step 1) with sealer and push it as far into the canal as possible.
Note: Tip should be approximately 0.5mm from Working Length. Use the device to sear off excess cone material at the canal orifice. Use a hand plugger to condense the cone.

Step 4: CONDENSE CONE WITH THE DEVICE

Activate the button to bring the device to the desired temperature.
Note: 150℃ for Resin Glue and 200 ℃ for GP is recommended. Advance the Pen Tip apically until reaching the depth indicated by the rubber stop (Set in step 2). Release the button to allow the Pen Tip to begin cooling, while at the same time holding continuous apical pressure, hold for 5 seconds. Remove the Pen Tip from the canal.
Note: if there is a tendency for the cone to come out with the Pen Tip- activate the button to heat the Pen Tip again (allow it time to reach set temperature) before trying to remove the Pen Tip from the canal.

Step 5: CONDENSE SHORTENED CONE WITH HAND PLUGGER

Use a small hand plugger to condense the remaining cone apically. Set the rubber stop (same depth as Step 2) and condense the remaining material.

Cleaning, Disinfection and Sterilization

⚠ **Caution:**

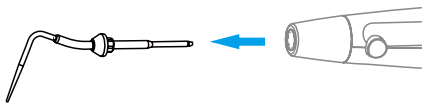
Cleaning, disinfection, and sterilization have limited impact on the reusable parts of the device. Therefore, the number of times the procedure is repeated is determined by the degree of wear of the part. If visual inspection reveals damaged parts, stop using them and purchase new parts from the manufacturer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



⚠ **Caution:**

Do not remove the Pen Tip immedicately after use until it cools down.

b. Flush the Pen Tip with running tap water (<40℃) until all visible residue is removed.