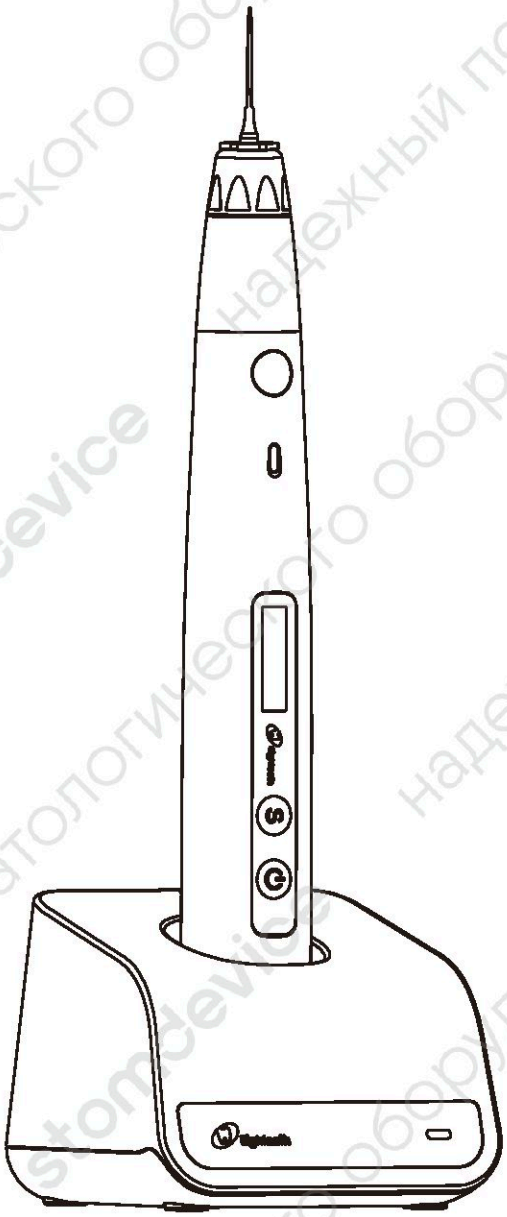
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Eighteeth

CE 0197



# Fast-Fill

# USER MANUAL

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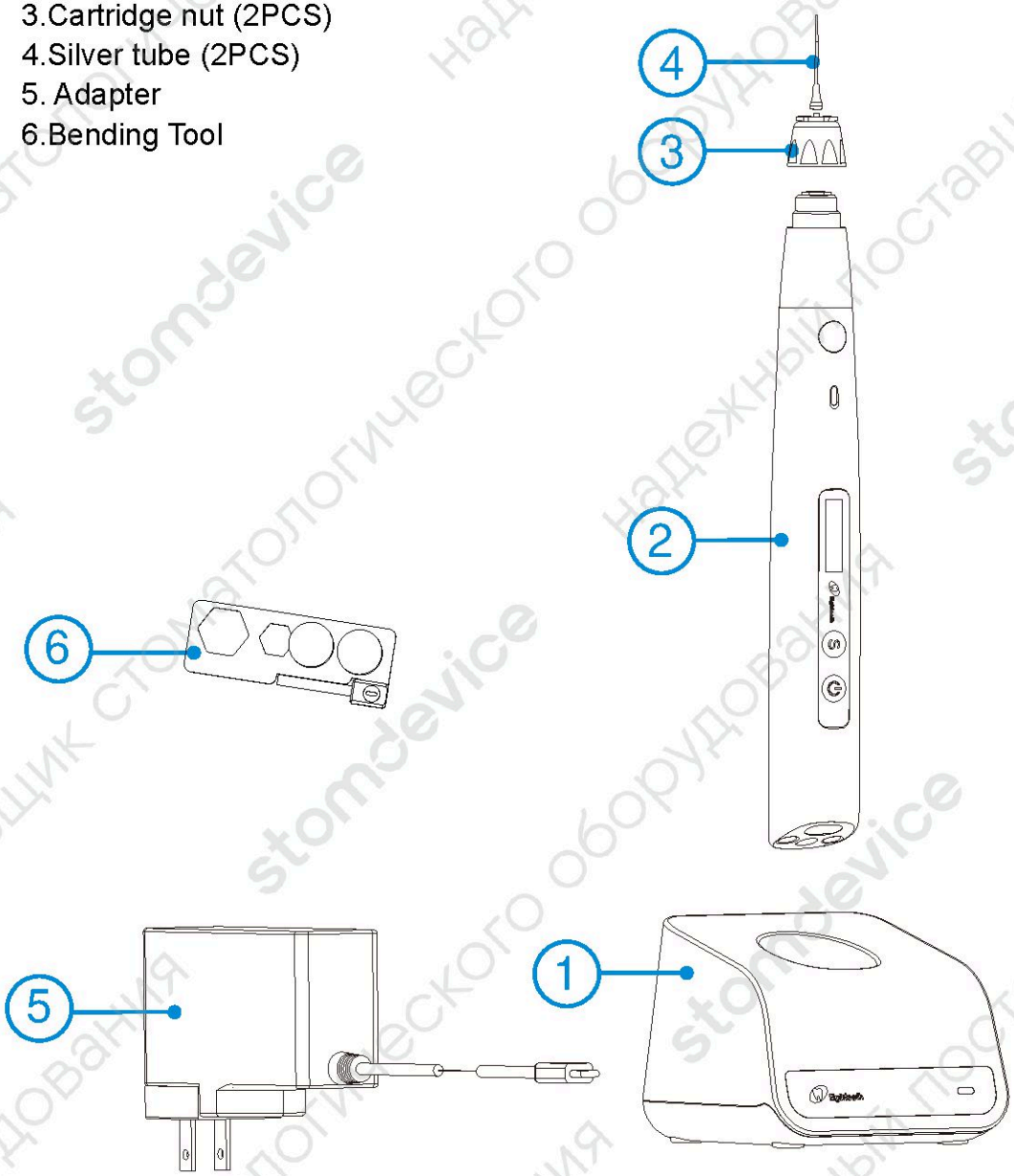


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# 1. Scope of Fast-Fill

## 1.1 Parts Identification

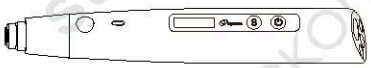
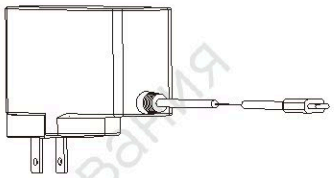
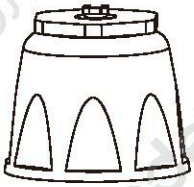
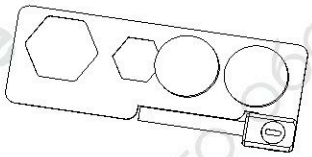
1.Charge Base
2.Handpiece
3.Cartridge nut (2PCS)
4.Silver tube (2PCS)
5. Adapter
6.Bending Tool



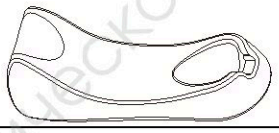



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## 1.2 Components and Accessories

| | | |
|---|---|---|
| Fast-Fill Handpiece (1pcs)<br>Part No. 6351002<br> | Charge Base (1pcs)<br>Part No. 6351003<br> | Adapter (1pcs)<br>Part No.6316001+6316005<br> |
| Cartridge nut (2pcs)<br>Part No. 6351207<br> | Bending tool (1pcs)<br>Part No. 6351010<br> | |
| Silver tube (1pcs)<br>Size: 25Ga<br>Color: Black<br>Part No. 6351208 **(Disposable)**<br> | Silver tube (1pcs)<br>Size: 23Ga<br>Color: Natural<br>Part No. 6351209 **(Disposable)**<br> | |

## 1.3 Options (sold separately)

| | |
|---|---|
| Silver tube (1pcs)<br>Size: 20Ga<br>Color: Black<br>Part No. 6351211 **(Disposable)**<br> | Handpiece Base<br>Part No. 6005002<br> |



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# 2. Symbols used in the User Manual

| | |
|---|---|
| WARNING | If the instructions are not followed properly, operation may lead to hazards for the product or the user/patient. |
| NOTE | Additional information, explanation of operation and performance. |
| SN | Serial number |
| REF | Catalogue number |
| | Manufacturer |
| | Date of manufacture |
| LOT | Lot of manufacture |
| | Class II equipment |
| | Type B applied part |
| CE | CE marking |
| | Direct current |
| | WEEE directive marking |
| | Keep dry |
| 134℃ | Can be autoclaved up to a maximum temperature of 134° Celsius |
| EC REP | Authorized Representative in the European Community |
| 55℃ -20℃ | Temperature limitation |
| 80% 20% | Humidity limitation |
| 106kPa 70kPa | Atmospheric pressure limitation |
| Eighteeth | Manufacturer's LOGO |
| | Consult instructions for use |



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**Błąd! Użyj karty Narzędzia główne, aby zastosować 标题 1 do tekstu, który ma się tutaj pojawić. Błąd! Użyj karty Narzędzia główne, aby zastosować 标题 1 do tekstu, który ma się tutaj pojawić.**

| | |
|---|---|
|  | Washer-disinfector for thermal disinfection |



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# 3. Before Use

## 3.1 Intended Use

Fast-Fill is intended for heating and extruding Gutta-percha into cleaned and shaped canals during root canal treatment.

This device must only be used in hospital environments, clinics or dental offices by qualified dental personnel and not used in the oxygen-rich environment.

## 3.2 Contraindications

This device must not be used in cases where a patient has been fitted with an implanted heart pacemaker (or other electrical equipment) and has been cautioned against the use of small electrical appliances (such as electric shavers, hair dryers, etc.)

Safety and effectiveness have not been established in pregnant women and children.

***WARNING***

Read the following warnings before use:

1. The device must not be placed in humid surroundings or anywhere where it can come into contact with any type of liquids.

2. Do not expose the device to direct or indirect heat sources. The device must be operated and stored in a safe environment.

3. The device requires special precautions with regard to electromagnetic compatibility (EMC) and must be installed and operated in strict compliance with the EMC information. In particular, do not use the device in the vicinity of fluorescent lamps, radio transmitters, remote controls and do not use this system near the active HF Surgical Equipment in the hospital. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Fast-Fill, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result. Do not charge, operate or store at high temperatures. Comply with the specified operating and storage conditions.

4. Gloves and a rubber dam are compulsory during treatment.

5. If irregularities occur in the device during treatment, switch it off. Contact the agency.

6. Never open or repair the device yourself, otherwise, void the warranty.

7. Cautions should be exercised when use the device to fill the teeth with thin dentinal root walls.



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# 4.Installing the Fast-Fill



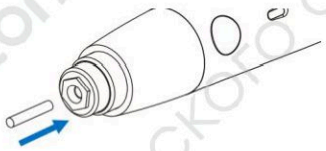
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## 4.1 Installation of Gutta-percha

Push the Gutta-percha into the handpiece.

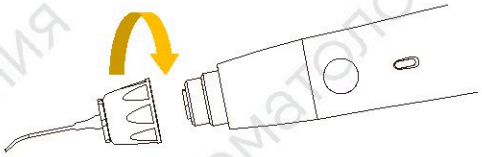


**NOTE**

This product is not included the Gutta-percha. Please use the Gutta-percha that is recommended by Sifary. Refer to the Technical data of this manual for the recommended Gutta-percha size.

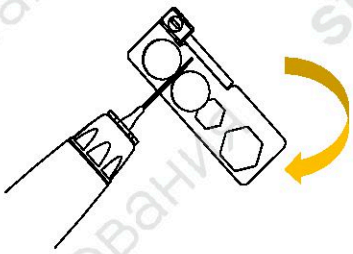
## 4.2 Installation of Cartridge

Screw the cartridge along the thread of the handpiece to install.

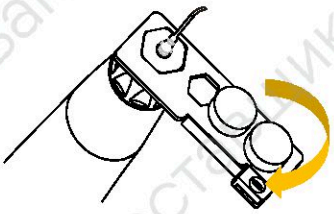


The needle on cartridge cannot be turned or bended by hand.

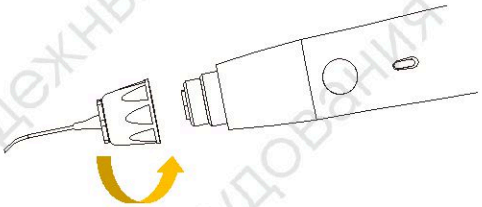
Use bending tool to bend the needle.



Use bending tool with the hexagonal hole matched to rotate the needle.

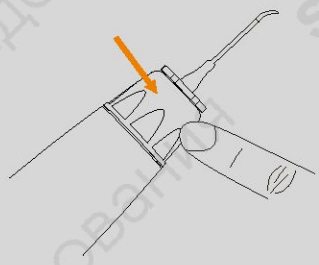


Unscrew the cartridge from the handpiece to disassemble.

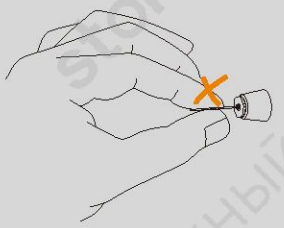


**WARNING**

- To remove the cartridge. As shown in the picture, touch the flow heater with finger rapidly, make sure it is not hot before operation. If the temperature is too high, waiting 3~5 minutes till it is cooling.



- Even if the cartridge cools down already, we strongly recommend not to touch the needle on cartridge. There is a risk of heat injury or damage the cartridge. Hold the black shell to remove.

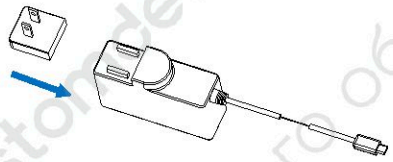




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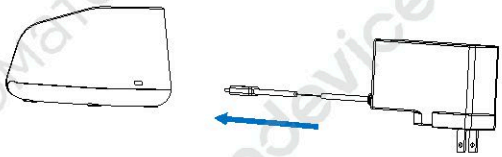
## 4.3 Installation of adapter

Plug the head into the base if they are separated in the package.

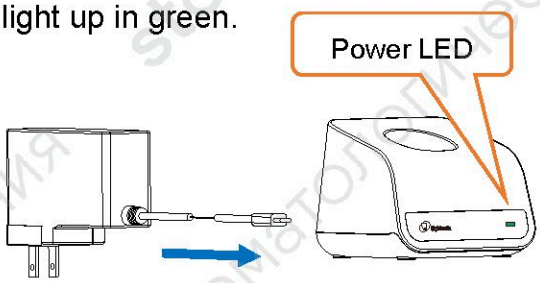


## 4.4 Connecting charge base

Plug the USB of adapter into the charge base, and plug the other end into a power outlet.



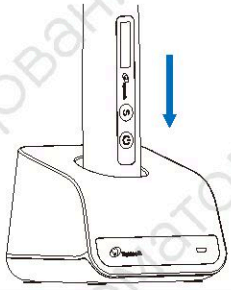
The Power LED on charge base will light up in green.




**NOTE**

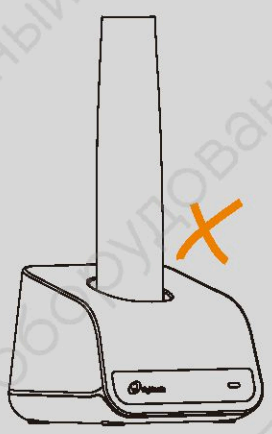
Only the original adapter could be used.

Put the handpiece all the way into the charge base. The charge state will show on the screen.

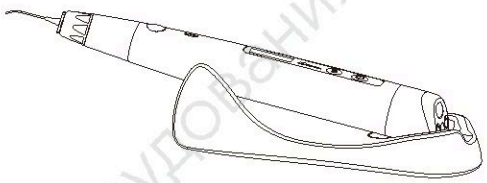


**NOTE**

Put the handpiece into the charge base in the right direction, otherwise the handpiece will not be charged.



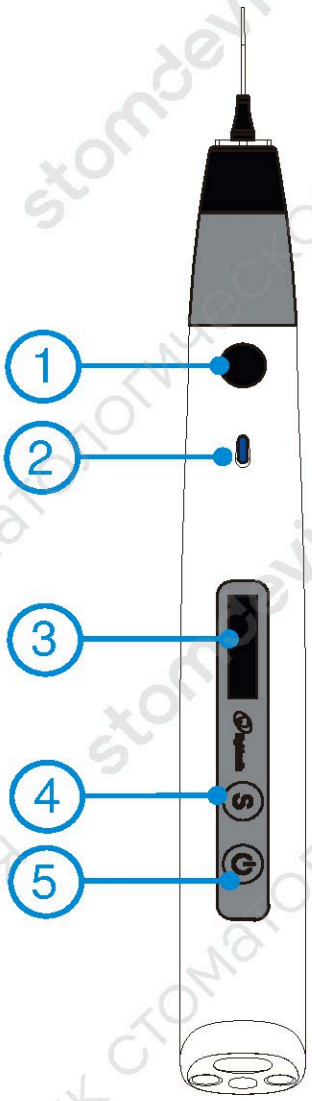
If only need a base to put the device on dentist element of dental chair (without charge function), handpiece base is recommended to use instead of charge base.





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# 5.Use Interface




○,1 ● Main switch

○,2 Indicator light

○,3 Display Screen

○,4 Ⓢ Set switch

○,5 ⏻ Power switch

**Turn Power On**

Long press ⏻ .

**Change Memory**

Shot press Ⓢ to change temperature memory from T1 to T3.

**Memory Parameter Setting**

During standby state, holding down press Ⓢ more than 2 seconds to enter memory parameter setting. Parameter T1 to T3 can be set independently. Press Ⓢ till target setting, press ● to adjust, then press Ⓢ to confirm.

**Heating**

During standby state, shot press ● and the indicator light flashes.

**Stop heating**

During heating state, shot press ⏻.

**Pushing out Gutta-percha**

When the heating is completed, the indicator light will be on. Holding down press ●.

**Turn Power Off**

Long press ⏻ more than 2 seconds.

**Advanced setting**

During power off state, holding down press ● then press ⏻ to enter advanced setting. Press



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| | |
|---|---|
| | Ⓢ till target setting, press ● to adjust, then press Ⓢ to confirm. |



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# 6.Setting

## 6.1 Memory Parameter Setting

| | |
|---|---|
|  | Fast-Fill has 3 memory programs (T1,T2,T3), press Ⓢ to change during standby state, the memory number will change accordingly. |
|  | During any memory, holding down press Ⓢ in 2 seconds, the “Temperature” of this memory can be changed.<br>Press ● till target temperature, the temperature can be set from 100℃ to 200℃.<br>Press Ⓢ to confirm and enter next interface. |
|  | The “Push Speed” of this memory can be changed.<br>Press ● till target speed, the speed can be set Low, Mid, High.<br>Press Ⓢ to confirm and enter next interface. |
|  | The “Change GP” can be chosen.<br>Confirm the Gutta-percha need to change or not, press ● to adjust.<br>If choose “No”, Press Ⓢ to confirm and return to standby interface.<br>If choose “Yes”, see chapter **7.3 Changing Gutta-percha** for more information. |



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## 6.2 Advanced Setting

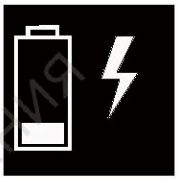
| | |
|---|---|
|  | During power off state, holding down press ● then press ⏻ to enter advanced setting, the "AutoPowerOff" will appear on the display screen.<br>Press ● to adjust, the auto power off time can be set to 5, 10 and 15 minutes.<br>Press Ⓢ to confirm and enter next interface. |
|  | The "Beep Volume" can be changed. Press ● to adjust. The "Beep Volume" can be set to 0, 1 and 2.<br>Press Ⓢ to confirm and enter next interface. |
|  | The "RestoreSettings" can be changed. Press ● to adjust, press Ⓢ to confirm and enter next interface.<br>**NOTE**<br>If choose "YES", all the setting parameters will be covered by factory settings. |
|  | The "Save" can be chosen.<br>Confirm the setting need to save or not, press ● to adjust, press Ⓢ to save and power off. |



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# 7.Operation

## 7.1 Charge

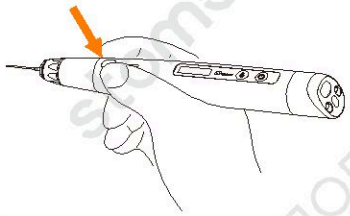
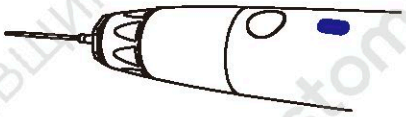
| | |
|---|---|
|  | Display the present remaining amount of the battery.<br>Less than 15% remains, please charge. |
| | **NOTE**<br>If the power if less than 15%, the device must be recharged within 30 days, otherwise the battery will be damaged. |
| <br>Alternative charging method | Charge without charge base is also available, connect adapter to handpiece directly, the charge state will show on the screen.<br>Charge with charge base is recommended **(See chapter 4.4 Connecting charge base)**<br>**NOTE**<br>Only the original adapter could be used.<br>Do not use the handpiece during the charging. |
|  | Charging indication appears on the screen, and flashes slowly, when battery is fully charged or in a state near full charge, the flash will stop. Fully charged will take about 4 hours, depending on residual battery power and battery state.<br>It can be recharged 300-500 times, depending on the operating conditions of the device.<br>**WARNING**<br>Do not change the battery, only trained technician or distributor can change the battery. The electronic parts will be |



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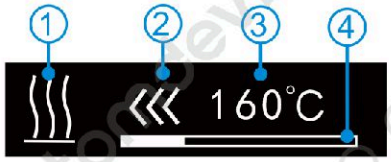
| | |
|---|---|
| | damaged if use a wrong battery or install with a wrong way. |

## 7.2 Heating and Using

| | |
|---|---|
|  | Shot press ● to heat the cartridge during standby state.<br>**NOTE**<br>Push out insufficiently warmed Gutta-percha about 10mm before each use. |
|  | The LED flashes in blue slowly during heating. When up to target temperature, the flash will stop and stay in blue.<br>**WARNING**<br>If the handpiece is not operated for a long time after the heating completed, press ⏻ to stop heating.<br>Do not place the heated cartridge in the root canal for more than 5 seconds to prevent thermal injury to the patient. |



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| | |
|---|---|
|  | ① Heating indication, When the set temperature is reached, heating process will switch off and " " will display on screen.<br>② Direction of pushing<br>③ Real time heating temperature<br>④ Gutta-percha residual |
|  | After heating completed, hold down press ● to push out Gutta-percha. At the same time, ① the light of direction flashes, ② the residual Gutta-percha bar will change according. Press ⏻ to exit and return to standby interface. |

**NOTE**

If there is a little residual Gutta-percha in handpiece or cartridge, tighten the cartridge again to prevent leak Gutta-percha after heating.

If there is too much residual Gutta-percha in handpiece or cartridge, please refer to daily cleaning process.

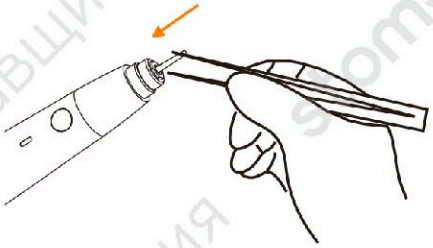
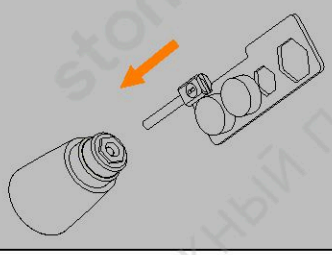
Please use good mobility Gutta-percha, otherwise the Gutta-percha will leak. If leaking please refer to daily cleaning process.

## 7.3 Changing Gutta-percha

| | |
|---|---|
|  | During standby state, holding down press Ⓢ in 2 seconds to entry memory parameter setting. Press Ⓢ till "Change GP". Press ● till "Yes" and press Ⓢ to confirm. |



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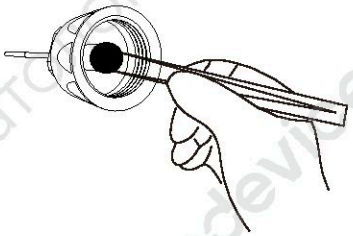
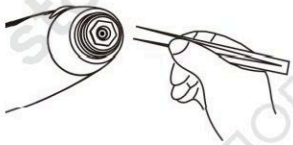
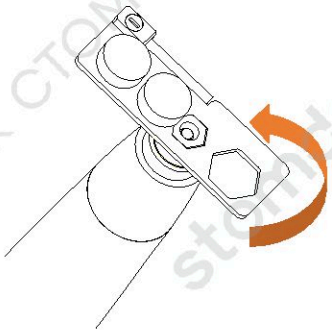
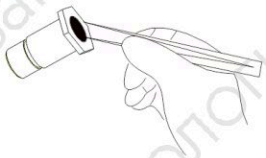
| | |
|---|---|
|  | Firstly, the handpiece will heat to about 150°C to melt the residual Gutta-percha. |
|  | Secondly, the pushrod pushes forward until the Gutta-percha is exhausted. the direction of push rod movement displays on the screen. |
|  | Then, the direction and position of push rod display on the screen. The push rod needs returning to original position. This operation needs about 50 seconds. |
|  | Finally, when the push rod is back to original position, “Please insert GP” will display on the screen. Press any key to exit and return to standby interface. |
| **NOTE**<br>During this state, press  can stop and return to standby interface. | |
|  | After pushing the Gutta-percha bar into handpiece with medical forceps, screw down the cartridge.<br>**NOTE**<br>If there is some Gutta-percha in the handpiece, it is inconvenient to install the Gutta-percha bar. Push the residue to the bottom of cavity with the pin on bending tool.<br> |



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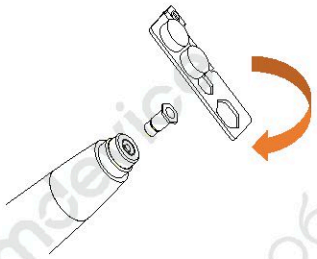
# 8.Maintenance

## 8.1 Piston cleaning

| Piston cleaning | |
|---|---|
|   | Heat to 150℃ to melt Gutta-percha, then remove the cartridge.<br>**NOTE**<br>A small amount of Gutta-percha residue have no effect of function. |
|  | Clean the residue inside the cartridge needle with medical forceps. |
|  | Clean the overflow Gutta-percha on the top of the handpiece with medical forceps. |
|  | When the medical forceps cannot get into the cavity to clean, Heat the handpiece to about 150℃, then unscrew the “Cleaning Nut” with the bending tool.<br>**NOTE**<br>Heating to 150℃ to avoid damaging the “Cleaning Nut”. |
|  | Clean the inside of nut with medical forceps. |

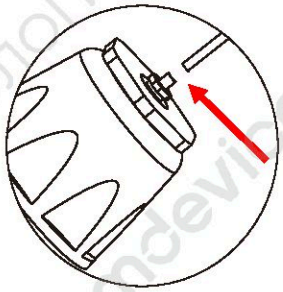
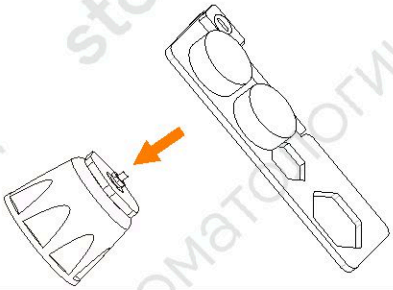
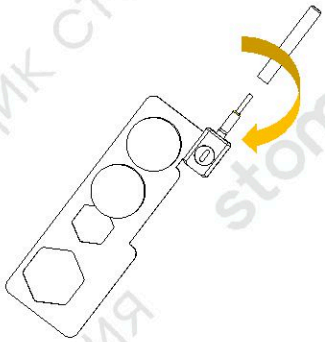


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| | |
|---|---|
|  | Heat the handpiece to about 150℃. Then install the “Cleaning Nut” to the handpiece after cleaning is completed. |

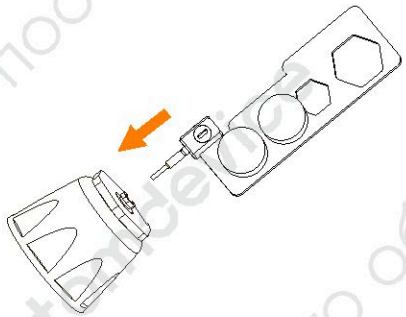
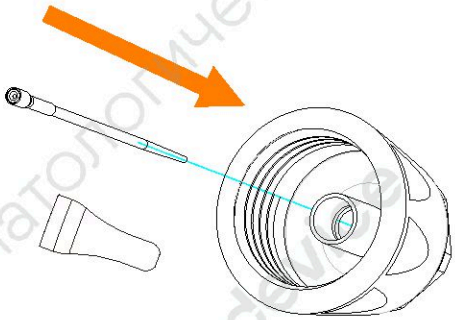
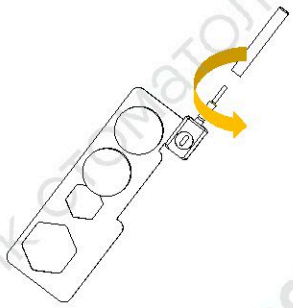
## 8.2 Changing silver tube of cartridge

The silver tubes of cartridge are single use only and should only be used on one patient. It can be replaced according to the following steps.

| | |
|---|---|
|  | Cut the broken silver tube from the step where the arrow indicates with knife. |
|  | Push out the silver tube with the bottom plane of the bending tool. |
|  | Unscrew the cap from the cleaning rod. |

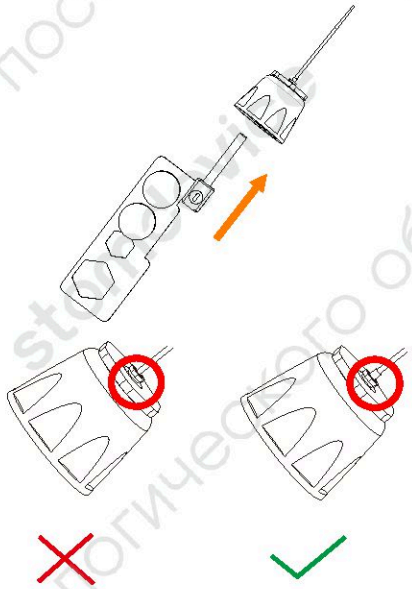
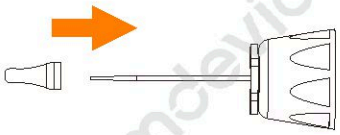


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| | |
|---|---|
|  | As shown, push out the silver tube completely with the cleaning rod. |
|  | Insert the new silver tube as shown in the figure.<br>**NOTE**<br>Remove the protective cover before installation.<br>There are two different specifications of the silver tube:<br>Part number:6351208 size: silver tube (25Ga)<br>Part number:6351209 size: silver tube (23Ga)<br>Need to order from distributor. |
|  | Screw the cap into the cleaning rod. |



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| | |
|---|---|
|  | Push the cleaning rod against the bottom of the silver tube and press it into place.<br>**NOTE**<br>If the installation is not in place, please contact the supplier to use professional tools for maintenance. |
|  | Push the protective cover into the silver tube. |

## 8.3 Cleaning, Disinfection and Sterilization

### 8.3.1 Foreword

The parts for clinical application contamination are the outer surfaces of the cartridge and bending tool. For hygiene and sanitary safety purpose, the components (cartridge and bending tool) must be cleaned, disinfected and sterilized before each usage to prevent any contamination. This concerns the first use as well as the subsequent uses.
Comply with your national guidelines, standards and requirements for cleaning, disinfection and sterilization.

### 8.3.2 General recommendations

- The user is responsible for the sterility of the product for the first cycle and each further usage as well as for the usage of damaged or dirty instruments, where applicable after sterility.
- For your own safety, please wear personal protective equipment (gloves, safety glasses, etc.).
- Use only a disinfecting solution which is approved for its efficacy (VAH/DGHM-listing, CE marking, and FDA approval) and in accordance with the DFU of the



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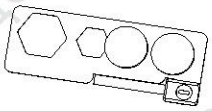
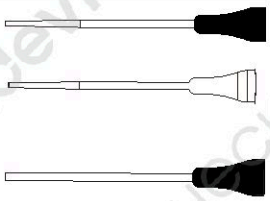
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disinfecting solution manufacturer.

- The water quality has to be convenient to the local regulations especially for the last rinsing step or with a washer-disinfector.
- Thoroughly clean and wash the components before autoclaving.
- Do not clean the cartridge with an ultrasonic cleaning device.
- Do not use bleach or chloride disinfectant materials.

### 8.3.3 Autoclavable Components

| **Autoclavable Components** | | | |
|---|---|---|---|
| Cartridge nut |  | Bending Tool |  |
| Silver tubes |  | | |

**WARNING**

- Only the components above can be autoclaved.
- Before first use and after each use, sterilize the above components.

| **STEP NO.** | **INSTRUCTIONS** | |
|---|---|---|
| 1 | Initial treatment at point of use | Immediately after using, wipe gross contaminations from the components and cut out the silver tube (refer to “Chapter 8.2-Changing silver tube of cartridge”), and put them in container for transportation.<br>Prepare the components directly after treatment.<br>**WARNING**<br>● Do not submerge the components or wipe them with any of the following functional water (acidic electrolyzed water, strong alkaline solution, or ozone water), medical agents (glutaral, etc.), or any other special types of water or commercial cleaning liquids. Such liquids may result in metal corrosion and adhesion of the residual medical |



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| | | |
|---|---|---|
| | | agents to the components.<br>● Silver tubes are single use only and shall be disposed of according to the local environmental protection laws and regulation. |
| 2 | Preparation before cleaning | Remove and disconnect the Cartridge nut before cleaning. Refer to "Chapter 4-Installing the Fast-Fill" of this manual for disassembly instructions.<br>**WARNING**<br>Observe suitable personal protective measures. |
| The following Step 3 to Step 5 are operated in a washer-disinfector:<br>**WARNING**<br>● Use only approved washer-disinfectors according to EN ISO 15883, maintain and calibrate it regularly.<br>● Follow instructions and observe concentrations given by the manufacturer (see general recommendations).<br>● Sufficient rinsing step should be available in purified water (max 10 germs/ml and max 0.25 endotoxin units/ml)<br>● Avoid any contact between the cartridge nut and any instrument, kit, support or container.<br>● Make sure the components are dry before moving to the #6 step. | | |
| 3 | Cleaning: Automated | Carefully put the components (Cartridge nut and Bending Tool) into the washer-disinfector and set the parameters as follows:<br>- Pre-cleaning: water temperature <30℃, 2 min;<br>- Cleaning: water temperature 45℃, 5 min; use an enzyme detergent solution (aldehyde free solution) which is suitable to be used with washer-disinfector, and use in accordance with the IFU of the detergent solution manufacturer;<br>- Rinsing: water temperature 45℃, 1 min (rinsing twice). |
| 4 | Disinfection: Thermal | Thermal disinfection at least 5 min at 90℃/194° F, make sure A0 value≥3000.<br>Rinse with purified water at 70°C for 1 minute. |
| 5 | Drying | Heat, 20min, 90℃/194° F |
| 6 | Maintenance and | Inspect components and sort out those with defects. Dirty components must be cleaned and disinfected |



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| | | |
|---|---|---|
| | Inspection | again. |
| 7 | Packaging | Pack each component in a separate steam-sterilization pouch.<br>**WARNING**<br>● Check the validity period of pouch given by the manufacturer to determine the shelf life.<br>● Use pouches which resist to a temperature up to 141°C(286°F) and in accordance with EN 868. |
| 8 | Sterilization | Steam sterilization at 134°C at least 5 minutes.<br>Minimum drying time after sterilization: 10 minutes.<br>**WARNING**<br>● Use only approved autoclave devices according to EN 13060 or EN 285.<br>● Use a validated sterilization procedure according to ISO 17665.<br>● Respect the maintenance procedure of the autoclave device given by the manufacturer.<br>● Use only this recommended sterilization procedure.<br>● Control the efficiency (packaging integrity, no humidity, color change of sterilization indicators, physicochemical integrators, digital records of cycles parameters).<br>● The sterilization procedure must comply with ISO 17665.<br>● Waiting for cooling before touching. |
| 9 | Storage | Keep the components in sterilization packaging in a dry and clean environment.<br>**WARNING**<br>● Sterility cannot be guaranteed if packaging is open, damaged or wet.<br>● Check the packaging before using it (packaging integrity, no humidity and validity period). |

*NOTE*

The instructions provided above have been validated by the manufacturer of the medical device as being capable of preparing a medical device for use. It remains the responsibility of the processor to ensure that the processing, as



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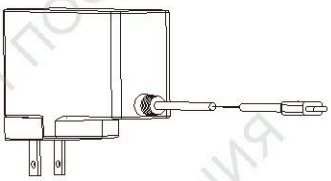


actually performed using equipment, materials and personnel in the processing facility, achieves the desired result. This requires verification and/or validation and routine monitoring of the process. Likewise, any deviation by the processor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences.



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## 8.3.4 Disinfection components

| **Disinfection components** | | |
|---|---|---|
| Fast-Fill Handpiece  | Charge Base  | Adapter  |
| Handpiece Base  | | |
| Wipe all the surfaces with a cloth lightly moistened with Ethanol for Disinfection (Ethanol 70 to 80 vol%) at least 2min, repeat for 5 times. | | |
| ***NOTE***<br>● Do not use anything except Ethanol for Disinfection (Ethanol 70 to 80 vol%).<br>● Do not use too much ethanol as it's going into machine and damage the components inside.<br>● Do not spray any liquid directly on the handpiece. Do not allow any moisture to get into the handpiece. | | |



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# 9.Troubleshooting

When trouble is found, check the following points before contacting your distributor. If none of these are applicable or the trouble is not remedied even after action has been taken, the product may have failed. Contact your distributor.

| Problem | Cause | Solution | Ref. chap |
|---|---|---|---|
| The power is not turned on. | The battery is flat. | Charge the battery. | 7.1 |
| | Press the power switch too short time. | Long press the power switch. | 5 |
| The power LED on charge base does not light. | Using a wrong adapter. | Use the original adapter. | 4.3 |
| | The adapter is not connected. | Check the connection. | 4.3 |
| | The plug of the adapter is not inserted into the outlet. | Check the connection. | / |
| | There is no electricity in the outlet. | Check the connection. | / |
| No charge indicator flash on handpiece screen. | Put the handpiece into the charge base in the wrong direction. | Check the direction. | 4.4 |
| | Charge pin of charge base is unable to rebound. | Remove debris which between move part and base of the charge pin. | / |
| | Contactors are dirty. | Cleaning the surface of contactors. | / |
| | The charge base is broken. | Connect adapter to handpiece directly, and contact your distributor. | / |
| Handpiece screen does not appear. | The handpiece is broken. | Check if there is a sound of beep, and contact your distributor. | / |
| No sound. | Beep volume is set to 0. | Set beep volume to 1, 2 or 3. | 6.2 |
| No gutta percha out. | The cartridge is broken. | Use a new cartridge. | / |



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# 10.Technical Data

| | |
|---|---|
| Manufacturer | Changzhou Sifary Medical Technology Co.,Ltd |
| Model | Fast-Fill |
| Dimensions | 23cm x 17cm x 8cm±1cm (Outer box) |
| Gutta-percha size | Diameter：2.5mm-2.8mm<br>Length：14mm-16mm<br>Applicable temperature: 100℃-200℃ |
| Weight | 1.1kg±10% |
| Power supply | Lithium ion battery: 3.7V, 2600mAh, ±10% |
| Charger power supply | AC 100-240 V, ±10% |
| Charger power output | 6V⎓3A |
| Frequency | 50/60Hz, ±10% |
| Temperature | 100℃~200℃ |
| Electrical safety class | Class II |
| Applied part | B |
| Operating conditions | Use: in enclosed spaces<br>Ambient temperature: 5°C ~ 40 °C<br>Relative humidity: <80%<br>Operating altitude < 3000m above sea level<br>Atmospheric pressure: 70kPa-106kPa |
| Transport and storage conditions | Ambient temperature: -20 °C ~ +55 °C<br>Relative humidity: 20% ~ 80 %<br>Atmospheric pressure: 70kPa~106kPa |



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# 11.EMC Tables

| **Guidance and manufacturer's declaration – electromagnetic emissions** | | |
|---|---|---|
| The **Fast-Fill** is intended for use in the electromagnetic environment specified below. The customer or the user of the **Fast-Fill** should assure that it is used in such an environment. | | |
| **Emissions test** | **Compliance** | **Electromagnetic environment - guidance** |
| RF emissions CISPR 11 | Group 1 | The **Fast-Fill** uses 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 emissions CISPR 11 | Class B | The **Fast-Fill** is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| Harmonic emissions IEC61000-3-2 | Class A | |
| Voltage fluctuations/flicker emissions IEC 61000-3-3 | Complies | |

| **Guidance and manufacturer's declaration – electromagnetic immunity** | | | |
|---|---|---|---|
| The **Fast-Fill** is intended for use in the electromagnetic environment specified below. The customer or the user of the **Fast-Fill** 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<br><br>+/- 2 kV, +/- 4 kV, +/- 8 kV, +/- 15 kV air | +/- 8 kV contact<br><br>+/- 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 %. |



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| | | | |
|---|---|---|---|
| Electrical fast transients/bursts IEC 61000-4-4 | ±2kV 100kHz repetition frequency | ±2kV 100kHz repetition frequency | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge IEC 61000-4-5 | Line to line: ±0.5kV, ±1kV<br><br>Line to earth: ±0.5kV, ±1kV, ±2kV | Line to line: ±0.5kV, ±1kV<br><br>Line to earth: ±0.5kV, ±1kV, ±2kV | Mains power quality should be that of a typical commercial or hospital environment. |
| Voltage dips IEC 61000-4-11<br><br><br><br><br><br><br><br>Voltage interruptions IEC 61000-4-11 | 0% UT; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°<br><br>0% UT; 1 cycle and 70% UT; 25/30 cycles sine phase at 0°<br><br>0% UT; 250/300 cycle | 0% UT; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°<br><br>0% UT; 1 cycle and 70% UT; 25/30 cycles sine phase at 0°<br><br>0% UT; 250/300 cycle | Mains power quality should be that of a typical commercial or hospital environment. If the user of devices require continued operation during power mains interruptions, it is recommended that devices be powered form an uninterruptible power supply or a battery |
| Rated Power frequency magnetic field IEC 61000-4-8 | 30 A/m 50Hz or 60Hz | 30 A/m 50Hz or 60Hz | Power frequency magnetic field should be at levels characteristic of a typical location in a typical commercial or hospital environment. |
| Note: UT: rated voltage(s); E.g. 25/30 cycles means 25 cycles at 50Hz or 30 cycles at 60Hz | | | |

| **Guidance and manufacturer's declaration – electromagnetic immunity** | | | |
|---|---|---|---|
| The **Fast-Fill** is intended for use in the electromagnetic environment specified below. The customer or the user of the **Fast-Fill** should assure that it is used in such an environment. | | | |
| **Immunity test** | **IEC 60601 test level** | **Compliance level** | **Electromagnetic environment - guidance** |



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| | | | |
|---|---|---|---|
| Conducted disturbances induced by RF fields IEC 61000-4-6 | 3 V 0.15 MHz – 80 MHz, 6 V in ISM bands between 0.15 MHz and 80 MHz, 80 % AM at 1 kHz | 3 V | Portable and mobile RF communications equipment should be usedno closer to any part of the **Fast-Fill**, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. |
| Radiated RF EM fields IEC 61000-4-3 | 3 V/m, 80 MHz – 2,7 GHz, 80 % AM at 1 kHz | 3V/m | **Recommended minimum separation distances** See the RF wireless communication equipment table in "Recommended minimum separation distances" |
| Proximity fields from RF wireless communication equipment IEC 61000-4-3 | See the RF wireless communication equipment table in "Recommended minimum separation distances" | Complies | |

**Recommended minimum separation distances**

Nowadays, many RF wireless equipments have being used in various healthcare locations where medical equipment and/or systems are used. When they are used in close proximity to medical equipment and/or systems, the medical equipment and/or systems' basic safety and essential performance may be affected. The **Fast-Fill** has been tested with the immunity test level in the below table and meet the related requirements of IEC 60601-1-2:2014. The customer and/or user should help keep a minimum distance between RF wireless communications equipments and the **Fast-Fill** as recommended below.

| Test frequency (MHz) | Band (MHz) | Service | Modulation | Maximum power (W) | Distance (m) | Immunity test level (V/m) |
|---|---|---|---|---|---|---|
| 385 | 380-390 | TETRA 400 | Pulse modulation 18Hz | 1.8 | 0.3 | 27 |



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| | | | | | | |
|---|---|---|---|---|---|---|
| 450 | 430-470 | GMRS 460<br>FRS 460 | FM<br>± 5 kHz<br>deviation<br>1 kHz sine | 2 | 0.3 | 28 |
| 710<br>745<br>780 | 704-787 | LTE Band 13, 17 | Pulse<br>modulation<br>217Hz | 0.2 | 0.3 | 9 |
| 810<br>870<br>930 | 800-960 | GSM 800/900,<br>TETRA 800,<br>iDEN 820,<br>CDMA 850,<br>LTE Band 5 | Pulse<br>modulation<br>18Hz | 2 | 0.3 | 28 |
| 1720<br>1845<br>1970 | 1700-1990 | GSM 1800;<br>CDMA 1900;<br>GSM 1900;<br>DECT;<br>LTE Band 1, 3, 4, 25; UMTS | Pulse<br>modulation<br>217Hz | 2 | 0.3 | 28 |
| 2450 | 2400-2570 | Bluetooth,<br>WLAN,<br>802.11 b/g/n,<br>RFID 2450,<br>LTE Band 7 | Pulse<br>modulation<br>217Hz | 2 | 0.3 | 28 |
| 5240<br>5500<br>5785 | 5100-5800 | WLAN 802.11 a/n | Pulse<br>modulation<br>217Hz | 0.2 | 0.3 | 9 |

***WARNING***

1. Use of accessories and cables other than those specified or provided by the manufacturer of **Fast-Fill** could result in increased electromagnetic emissions or decreased electromagnetic immunity of **Fast-Fill** and result in improper operation.
   **Cable information:**

| Cable Name | Cable Length (m) | Shielded or not | Remark |
|---|---|---|---|
| Adapter Cable | 2 | No | / |

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



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# 12.Statement

**Service Life**

The service life of Fast-Fill series products is 3 years.

**Maintenance**

MANUFACTURE will provide circuit diagrams, component part lists, descriptions, calibration instructions to assist to SERVICE PERSONNEL in parts repair.

**Disposal**

The package should be recycled. Metal parts of the device are disposed as scrap metal. Synthetic materials, electrical components, and printed circuit boards are disposed as electrical scrap. The lithium batteries are disposed as special refuse. Please deal with them according to the local environmental protection laws and regulation.

**Rights**

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