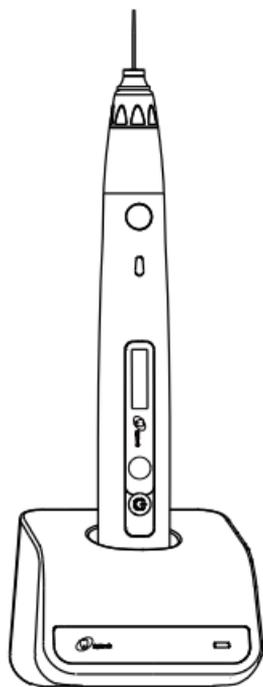




CE
0197



Fast-Fill

USER MANUAL

P/N: IFU-6335104

Version: 10

Issued: 2025.04.02

Size: 85mm×119mm

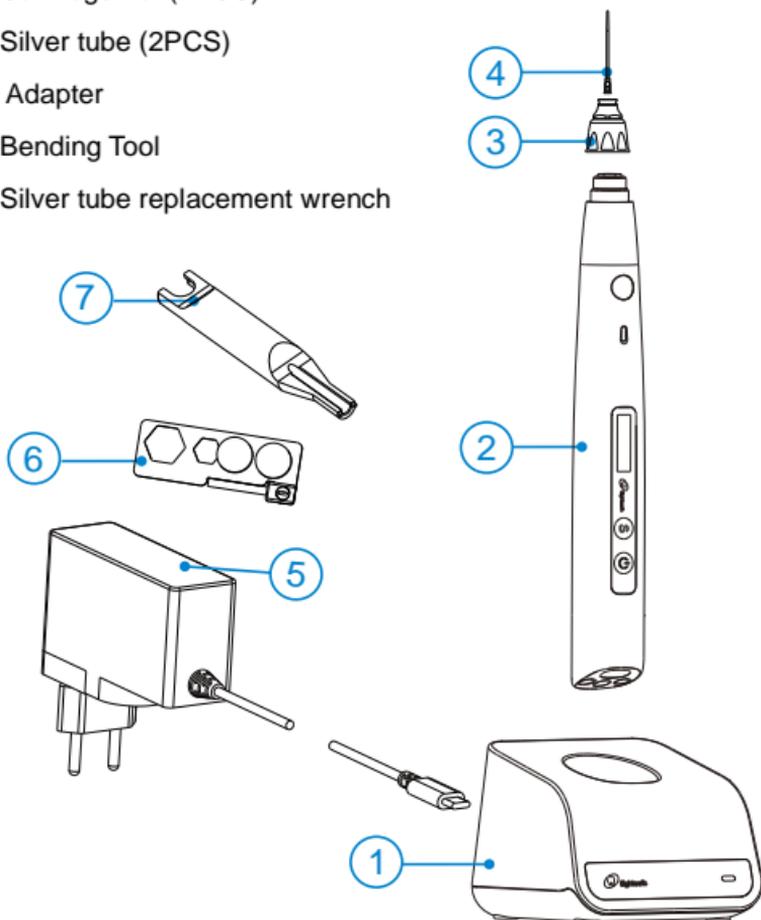
Content

1. Scope of Fast-Fill	4
1.1 Parts Identification.....	4
1.2 Components	5
2. Symbols used	8
3. Before Use	11
3.1 Scope of application.....	11
3.2 Contraindications	11
4. Installing the Fast-Fill	13
4.1 Installation of Gutta-percha	13
4.2 Installation of Cartridge	13
4.3 Installation of adapter.....	14
4.4 Connecting charge base	14
5. Use Interface	15
6. Setting	16
6.1 Memory Parameter Setting.....	16
6.2 Advanced Setting	17
7. Operation	18
7.1 Charge.....	18
7.2 Heating and Using.....	19
7.3 Changing Gutta-percha	20
8. Maintenance	22
8.1 Piston cleaning.....	22
8.2 Changing silver tube of cartridge	23
8.3 Cleaning, Disinfection and Sterilization.....	25
9. Error Indication	34
10. Troubleshooting	35
11. Technical Data	37
12. EMC Tables	38
13. Statement	45

1. Scope of Fast-Fill

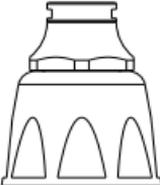
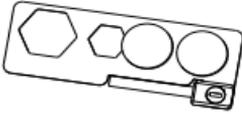
1.1 Parts Identification

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



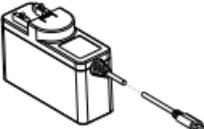
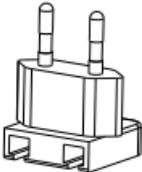
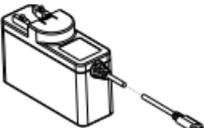
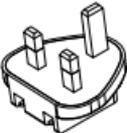
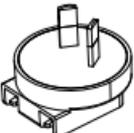
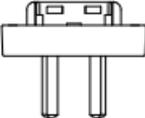
1 Scope of Fast-Fill

1.2 Components

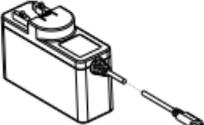
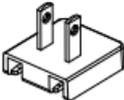
<p>Fast-Fill Handpiece (1 pc) Part No: 6351002</p> 	<p>Charge Base (1 pc) Part No: 6351003</p> 	<p>Silver tube replacement wrench(1 pc) Part No: 6351112</p> 
<p>Cartridge nut (2 pcs) Part No: 6351207</p> 	<p>Bending tool (1 pc) Part No: 6351106</p> 	<p>Silver tube (1 pc) Size: 23Ga (Disposable) Part No: 6351209</p> 
<p>Silver tube (1 pc) Size: 25Ga (Disposable) Part No: 6351208</p> 		

1 Scope of Fast-Fill

For different regions, there are several different adapter options to be selected as follows.

Standard	Adapter	Power plug
<p>European standard</p>	<p>Adapter (1 pc) Part No: 6316012</p> 	<p>European standard power plug (1 pc) Part No: 6316005</p> 
<p>Multi-standard</p>	<p>Adapter (1 pc) Part No: 6316012</p> 	<p>British standard power plug (1 pc) Part No: 6316006</p> 
		<p>Australian standard power plug (1 pc) Part No: 6316007</p> 
		<p>Argentina standard power plug (1 pc) Part No: 6316011</p> 

1 Scope of Fast-Fill

<p>American standard</p>	<p>Adapter (1 pc)</p> <p>Part No: 6316012</p> 	<p>American standard power plug (1 pc)</p> <p>Part No: 6316008</p> 
-------------------------------------	--	---

2. Symbols used

	General warning sign
	Caution
	Serial number
	Catalogue number
	Batch code
	Medical device
	Authorized representative in the European Community
	Manufacturer
	Country of manufacture+ Date of manufacture
	Class II equipment
	Washer-disinfector for thermal disinfection
	Type B applied part
	Keep dry

2 Symbols used in the User Manual

 <p>0197</p>	CE marking
	Dispose of in accordance with the WEEE directive
	Direct current
	Consult instructions for use
	Manufacturer's Logo
	Sterilizable in a steam sterilizer (autoclave) at the temperature specified
	Temperature limit
	Humidity limitation
	Atmospheric pressure limitation
	Caution, hot surface

2 Symbols used in the User Manual



Do not reuse

3.Before Use

3.1 Scope of application

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.

3.2Contraindications

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.)

Do not use on patients with a known sensitivity to natural rubber latex or silver.

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



- Read the following warnings before use:
- The device must not be placed in humid surroundings or anywhere where it can come into contact with any type of liquids.
- Do not expose the device to direct or indirect heat sources. The device must be operated and stored in a safe environment.
- 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.
- Gloves and a rubber dam are compulsory during treatment.
- If irregularities occur in the device during treatment, switch it off. Contact the agency.
- Never open or repair the device yourself, repair only by trained dealer maintenance personnel , otherwise, void the warranty.
- The contact time should be less than 1min from the equipment surface 80mm away from the tip for patient side.
- Cautions should be exercised when use the device to fill the teeth with thin dentinal root walls and pay more caution at temperature settings above 185°C.

2 Symbols used in the User Manual

- If there is an adverse reaction, it is told to immediately stop using and treat.

4. Installing the Fast-Fill

4.1 Installation of Gutta-percha

Push the Gutta-percha into the handpiece.



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 silver tube on cartridge cannot be turned or bended by hand.

Use bending tool to bend the silver tube.



Use bending tool with the hexagonal hole matched to rotate the silver tube.



Unscrew the cartridge from the handpiece to disassemble.



Make sure the machine is not heating up. To remove the cartridge. As shown in the picture, touch the cartridge nut 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.

Do not remove the silver tube while the handpiece is heating, prevent the Gutta-percha leaking out and scald



The surface temperature of the cartridge will not exceed 60°C during operation.

Do not touch the needle while heating. Even if the cartridge cools down already, we strongly recommend not to touch the silver tube. There is a risk of heat injury or damaging the silver tube. Hold the black shell to remove.

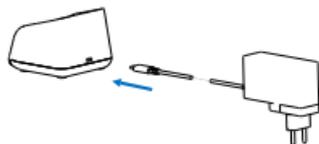
4.3 Installation of adapter

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

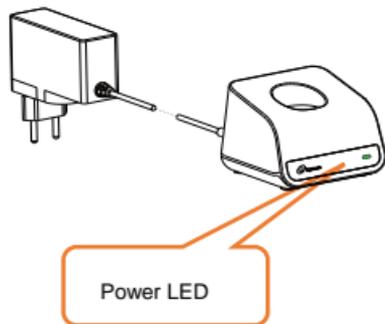


4.4 Connecting charge base

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

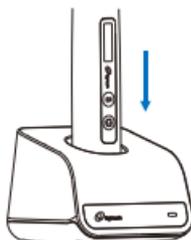


The Power LED on charge base will light up in green.



Only the original adapter can be used.

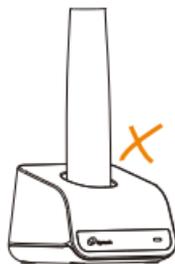
Put the handpiece all the way into the charge base. The charge state will show on the screen.



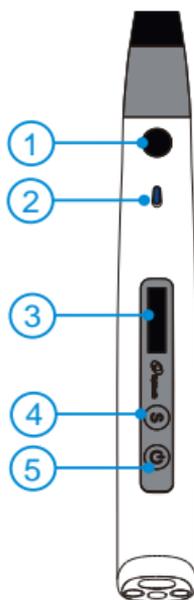
Put the handpiece into the charge base in the right direction, otherwise the handpiece will not be charged.



Don't position the device where it is difficult to operate the disconnection device



5. Use Interface



- ① Main switch
- ② Indicator light
- ③ Display Screen
- ④ S Set switch
- ⑤ Power switch

Turn Power On

Long press  .

Change Memory

Short 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, short press  and the indicator light flashes.

Stop heating

During heating state, short 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  till target setting, press  to adjust, then press  to confirm.

6.Setting

6.1Memory Parameter Setting

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

6.2 Advanced Setting

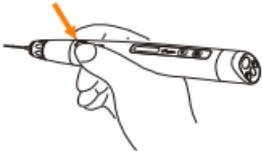
<p style="text-align: center;">AutoPowerOff 5 Min</p>	<p>During power off state, holding down press ●, then press ⏻ to enter advanced setting, the "AutoPowerOff" will appear on the display screen. Press ● to adjust, the auto power off time can be set to 5, 10 and 15 minutes.</p> <p>Press Ⓢ to confirm and enter next interface.</p>
<p style="text-align: center;">Beep Volume Vol 1</p>	<p>The "Beep Volume" can be changed. Press ● to adjust. The "Beep Volume" can be set to 0, 1 and 2.</p> <p>Press Ⓢ to confirm and enter next interface.</p>
<p style="text-align: center;">RestoreSettings NO YES</p>	<p>The "RestoreSettings" can be changed. Press ● to adjust, press Ⓢ to confirm and enter next interface.</p> <div style="background-color: #e0e0e0; padding: 5px; margin-top: 10px;">  <p>If choose "YES", all the setting parameters will be covered by factory settings.</p> </div>
<p style="text-align: center;">Save NO YES</p>	<p>The "Save" can be chosen.</p> <p>Confirm the setting need to save or not, press ● to adjust, press Ⓢ to save and power off.</p>

7.Operation

7.1Charge

	<p>Display the present remaining amount of the battery.</p> <p>Less than 15% remains, please charge.</p> <div style="background-color: #cccccc; padding: 5px; margin-top: 10px;">  </div> <p>If the power is less than 15%, the device must be recharged within 30 days, otherwise the battery will be damaged.</p>
 <p>Alternative charging method</p>	<p>Charge without charge base is also available, connect adapter to handpiece directly, the charge state will show on the screen.</p> <p>Charge with charge base is recommended (See chapter 4.4 Connecting charge base)</p> <div style="background-color: #cccccc; padding: 5px; margin-top: 10px;">  </div> <p>Only the original adapter could be used.</p> <p>Do not use the handpiece during the charging.</p>
	<p>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.</p> <p>It can be recharged 300-500 times, depending on the operating conditions of the device.</p> <div style="background-color: #cccccc; padding: 5px; margin-top: 10px;">  </div> <p>Do not change the battery, only trained technician or distributor can change the battery. The electronic parts will be damaged if use a wrong battery or install with a wrong way.</p>

7.2 Heating and Using

	<p>Short press ● to heat the cartridge during standby state.</p> <div style="background-color: #cccccc; padding: 5px; text-align: center;">  </div> <p>Push out insufficiently warmed Gutta-percha about 10mm before each use.¹</p>
	<p>The LED flashes in blue slowly during heating. When up to target temperature, the flash will stop and stay in blue.</p> <div style="background-color: #cccccc; padding: 5px; text-align: center;">  </div> <p>If the handpiece is not operated for a long time after the heating completed, press ⏻ to stop heating.¹</p>
	<p>① Heating indication. When the set temperature is reached, heating process will switch off and “<input checked="" type="checkbox"/>” will display on screen.</p> <p>② Direction of pushing</p> <p>③ Real time heating temperature</p> <p>④ Gutta-percha residual</p>
	<p>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.</p>



- 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

	<p>During standby state, holding down press  in 2 seconds to enter memory parameter setting. Press  till "Change GP". Press  till "Yes" and press  to confirm.</p>
	<p>Firstly, the handpiece will heat to about 150°C to melt the residual Gutta-percha.</p>
	<p>Secondly, the pushrod pushes forward until the Gutta-percha is exhausted. The direction of push rod movement displays on the screen.</p>
	<p>Then, the direction and position of push rod display on the screen. The push rod needs returning to original position. This operation takes about 50 seconds.</p>
	<p>Finally, when the pushrod is back to original position, "Please insert GP" will display on the screen. Press any key to exit and return to standby interface.</p> <div data-bbox="440 1068 512 1135" style="text-align: center;"> </div> <p>During this state, press  can stop and return to standby interface.</p>

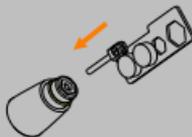
8 Maintenance



After pushing the Gutta-percha bar into handpiece with medical forceps, screw down the cartridge.

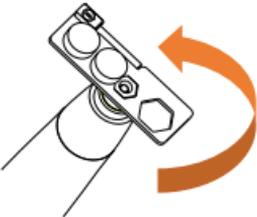


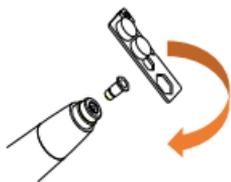
If there is some Gutta-percha in the handpiece, it is inconvenient to install the Gutta-percha bar. Push the residue to the bottom of cavity with the pin on bending tool.



8.Maintenance

8.1Piston cleaning

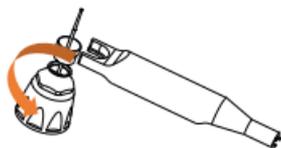
Piston cleaning	
	<p>Heat to 150°C to melt Gutta-percha, then remove the cartridge.</p> <div style="background-color: #cccccc; padding: 5px;">  <p>A small amount of Gutta-percha residue have no effect of function.</p> </div>
	<p>Dispose of the silver tube and then clean the residue inside the cartridge nut with medical forceps.</p>
	<p>Clean the overflow Gutta-percha on the top of the handpiece with medical forceps.</p>
	<p>When the medical forceps cannot get into the cavity to clean, heat the handpiece to about 150°C, then unscrew the "Cleaning Nut" with the bending tool.</p> <div style="background-color: #cccccc; padding: 5px;">  <p>Heating to 150°C to avoid damaging the "Cleaning Nut".</p> </div>
	<p>Clean the inside of nut with medical forceps.</p>



Heat the handpiece to about 150°C. Then install the "Cleaning Nut" to the handpiece after cleaning is completed.

8.2 Changing silver tube of cartridge

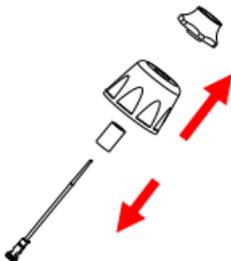
The silver tubes of cartridge are single use only and should only be used on one patient. It can be replaced according to the following steps.



Unscrew the top cover .



Unscrew the clamp nut. Remove two steel balls



Remove the used silver tube



Observe suitable personal protective measures.

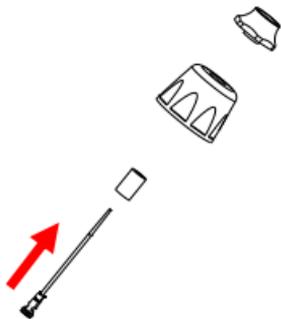
The Silver Tube is single use only and shall be disposed of according to the local environmental protection laws and regulation after use.



Use tweezers to clean the gutta percha in the Silver tube mounting holer



Use tweezers to clean the gutta percha in the shell



Insert the new silver tube as shown in the figure.

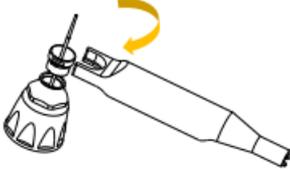


There are two different specifications of the silver tube:

Part number:6351208 size: silver tube (25Ga)

Part number:6351209 size: silver tube (23Ga)

Need to order from distributor.

	<p>Screw the clamp nut. Then Place two steel balls into the holes in the clamp nut</p> <div style="background-color: #cccccc; padding: 5px;">  <p>Normal use is not affected if steel balls are not installed</p> </div>
	<p>Screw the top cover.</p>

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.

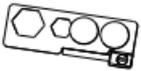
Comply with your national guidelines, standards and requirements for cleaning, disinfection and sterilization.

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 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 use bleach or chloride disinfectant materials.

8.3.3 Autoclavable Components

Autoclavable Components			
Cartridge nut Silver tube (Install together)		Bending Tool	
Silver tube replacement wrench			
 <ul style="list-style-type: none"> ● Only the components above can be autoclaved. ● Before first use and after each use, sterilize the above components. 			
<p>The Cartridge Nut, Silver Tube and Bending Tool must be cleaned, disinfected and sterilized before first use following step 3 to step 9. After each use, please follow step 1 to step 9.</p>			
STEP NO.	INSTRUCTIONS		
1	Initial treatment at point of use	 <p>Immediately after using, wipe gross contaminations from the components. Prepare the components directly after treatment.</p> <p>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.</p>	

		of the residual medical agents to the components.
2	Preparation before cleaning	<p>Remove and disconnect the Cartridge from handpiece. Refer to "Chapter 4-Installing the Fast-Fill" of this manual for disassembly instructions. Then, cut out the Silver Tube from Cartridge. Refer to "Chapter 8.2-Changing silver tube of cartridge". Put them in container for transportation.</p>  <ul style="list-style-type: none"> ● Observe suitable personal protective measures. ● The Silver Tube is single use only and shall be disposed of according to the local environmental protection laws and regulation after use.
<p>The following Step 3 to Step 5 are operated in a washer-disinfector:</p>  <ul style="list-style-type: none"> ● Use only approved washer-disinfectors according to EN ISO 15883, maintain and calibrate it regularly. ● Follow instructions and observe concentrations given by the manufacturer (see general recommendations). ● Sufficient rinsing step should be available in purified water (max 10 germs/ml and max 0.25 endotoxin units/ml)ⁱⁱⁱ ● Avoid any contact between the cartridge nut and any instrument, kit, support or container. ● Make sure the components are dry before moving to the #6 step. 		
3	Transportation:	Safe storage and transportation to the reprocessing area to avoid any damage and contamination to the environment.
4	Preparation for Decontamination:	<p>The devices must be reprocessed in a disassembled state.</p> 

		Observe suitable personal protective measures.
5	Pre-Cleaning:	Do a manual pre-cleaning, until the components are visually clean. Submerge the components in a cleaning solution and flush the lumens with a water jet pistol with cold tap water for at least 10 seconds. Clean the surfaces with a soft bristol brush.
6	Cleaning:	<p>Regarding cleaning/disinfection, rinsing and drying, it is to distinguish between manual and automated reprocessing methods. Preference is to be given to automated reprocessing methods, especially due to the better standardizing potential and industrial safety.</p> <p>Automated Cleaning:</p> <p>Carefully put the components into the washer-disinfector on a tray and set the parameters as follows, then start the program:</p> <ul style="list-style-type: none"> • 4 min pre-washing with cold water (<40°C); • emptying • 5 min washing with a mild alkaline cleaner at 55°C; • emptying • 3 min neutralising with warm water (>40°C); • emptying • 5 min intermediate rinsing with warm water (>40°C); • emptying

		<p>The automated cleaning processes have been validated by using 0.5% neodisher MediClean forte (Dr. Weigert).</p> <p>Note Acc. to EN ISO 17664 no manual reprocessing methods are required for these devices. If a manual reprocessing method has to be used, please validate it prior to use.</p> <div style="background-color: #e0e0e0; padding: 10px;">  <ul style="list-style-type: none"> ● Use only approved washer-disinfectors according to EN ISO 15883, maintain and calibrate it regularly. ● Follow instructions and observe concentrations given by the manufacturer (see general recommendations). </div>
7	Disinfection:	<p>Automated Thermal Disinfection in washer/disinfector under consideration of national requirements in regards to A0 value (see EN ISO 15883). A disinfection cycle of 5 min disinfection at 93°C has been validated for the device to achieve an A0 value of 3000. After manual cleaning, the instruments should be automated disinfected or sterilized immediately. A manual disinfection is not recommended.</p>
8	Drying:	<p>Automated Drying:</p> <p>Drying of outside of instrument through drying cycle of washer/disinfector. If needed, additional manual drying can be performed through lint free towel. Insufflate cavities of instruments by using sterile compressed air.</p>
9	Functional Testing,	<p>Visual inspection for cleanliness of the instruments and reassembling. Functional testing according to instructions of</p>

	Maintenance:	<p>use. If necessary, perform reprocessing process again until instrument is visibly clean.</p> <p>Before packaging and autoclaving, make sure that the components have been maintained acc. to manufacturer's instruction.</p>
10	Packaging:	<p>Pack the instruments in an appropriate packaging material for sterilization.</p>  <ul style="list-style-type: none"> ● Check the validity period of pouch given by the manufacturer to determine the shelf life. ● Use pouches which resist to a temperature up to 141°C and in accordance with EN ISO 11607.
11	Sterilization:	<p>Sterilization of instruments by applying a fractionated pre-vacuum steam sterilization process (according to EN 285/EN 13060/EN ISO 17665) under consideration of the respective country requirements.</p> <p>Minimum requirements: 3 min at 134 °C (in EU: 5 min at 134 °C)</p> <p>Maximum sterilization temperature:137°C</p> <p>Drying time: at least 8min.</p> <p>Flash sterilization is not allowed on lumen instruments!</p>  <ul style="list-style-type: none"> ● Use only approved autoclave devices according to EN

		<p>13060 or EN 285.</p> <ul style="list-style-type: none"> ● Use a validated sterilization procedure according to EN ISO 17665. ● Respect the maintenance procedure of the autoclave device given by the manufacturer. ● Use only this recommended sterilization procedure. ● Control the efficiency (packaging integrity, no humidity, color change of sterilization indicators, physicochemical integrators, digital records of cycles parameters). ● The sterilization procedure must comply with EN ISO 17665. ● Waiting for cooling before touching.
12	Storage:	<p>Storage of sterilized instruments in a dry, clean and dust free environment at modest temperatures, refer to label and instructions for use.</p>  <ul style="list-style-type: none"> ● Sterility cannot be guaranteed if packaging is open, damaged or wet. ● Check the packaging before using it (packaging integrity, no humidity and validity period).
13	Reprocessing validation study information:	<p>The above-mentioned reprocessing process (cleaning, disinfection, sterilization) has been successfully validated. Refer to test reports: Changzhou Sifary _Cleaning Disinfection Validation Report</p>

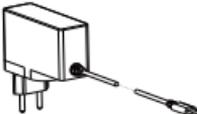
	No.
--	-----



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 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.

8.3.4 Disinfection components

Disinfection components		
Fast-Fill Handpiece	Charge Base	Adapter
		
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.		





- Do not use anything except Ethanol for Disinfection (Ethanol 70 to 80 vol%).
- Do not use too much ethanol as it's going into machine and damage the components inside.
- Do not spray any liquid directly on the handpiece. Do not allow any moisture to get into the handpiece.

9. Error Indication

 Low power	<p>When the battery is nearly empty, Press the Main switch● , this warning will appear on the screen, and the device does not start.</p> <p>Charge the device and return to normal</p>
---	--

10.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.	/
The power LED on charge base does not light.	Using a wrong adapter.	Use the original adapter.	4.4
	The adapter is not connected.	Check the connection.	/
	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.	/

11. Technical Data

Manufacturer	Changzhou Sifary Medical Technology Co.,Ltd.
Model	Fast-Fill
Dimensions	25cm x 10cm x 11cm ± 1cm (package)
Gutta-percha size	Diameter: 2.5mm-2.8mm Length: 14mm-16mm Applicable temperature: 100°C-200°C
Gross Weight	1.1kg ± 10%
Power supply	Lithium ion battery: 3.7V, 2600mAh, ± 10%
Charger power input	AC 100-240 V, ± 10%
Charger power input	500mA
Charger power output	6V $\overline{\dots}$ 3A
Frequency	50/60Hz, ± 10%
Temperature	100°C~200°C
Electrical safety class	Class II
Applied part	B (Cartridge nut , Silver tube)
Operating conditions	Use: in enclosed spaces Ambient temperature: 10°C ~ 40 °C Relative humidity: 30% ~ 75% Atmospheric pressure: 70kPa-106kPa
Transport and storage conditions	Ambient temperature: -20 °C ~ +55 °C Relative humidity: 20% ~ 80 % Atmospheric pressure: 70kPa~106kPa

12.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	Professional healthcare facility environment and Home healthcare environment.
RF emissions CISPR 11	Class A	
Harmonic emissions IEC61000-3-2	Class A	Professional healthcare facility environment.
Voltage fluctuations/flicker emissions IEC 61000-3-3	Compliances	
 <p>The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.</p>		

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 +/- 2 kV, +/- 4 kV, +/- 8 kV, +/- 15 kV air	+/- 8 kV contact +/- 2 kV, +/- 4 kV, +/- 8 kV, +/- 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast 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	Surges Line to line: ±0.5kV, ±1kV Surges Line to earth: ±0.5kV, ±1kV, ±2kV	Line to line: ±0.5kV, ±1kV 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	0% UT; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0% UT; 1 cycle and 70% UT; 25/30 cycles sine phase at 0°	0% UT; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0% UT; 1 cycle and 70% UT; 25/30 cycles sine phase at 0°	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 from an uninterruptible power supply or a battery

Voltage interruptions IEC 61000-4-11	0% UT; 250/300 cycle	0% UT; 250/300 cycle	
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

<p>Conducted disturbances induced by RF fields</p> <p>IEC 61000-4-6</p>	<p>3 V</p> <p>0.15 MHz – 80 MHz, 6 V in ISM bands and amateur radio bands between 0.15 MHz and 80 MHz, 80 % AM at 1 kHz</p>	<p>3 V</p>	<p>Portable and mobile RF communications equipment should be used no 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.</p> <p>Recommended minimum separation distances</p>
<p>Radiated RF EM fields</p> <p>IEC 61000-4-3</p>	<p>3 V/m, 80 MHz – 2,7 GHz, 80 % AM at 1 kHz</p>	<p>3V/m</p>	<p>See the RF wireless communication equipment table in "Recommended minimum separation distances"</p>
<p>Proximity fields from RF wireless communication equipment</p> <p>IEC 61000-4-3</p>	<p>See the RF wireless communication equipment table in "Recommended minimum separation distances"</p>	<p>Complies</p>	

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 60601-1-2:2020. 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
450	430-470	GMRS 460 FRS 460	FM± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704-787	LTE Band 13, 17	Pulse modulation 217Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900, TETRA 800, IDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT;	Pulse modulation 217Hz	2	0.3	28
1845						
1970						

		LTE Band 1, 3, 4, 25; UMTS				
2450	2400- 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217Hz	2	0.3	28
5240	5100- 5800	WLAN 802.11 a/n	Pulse modulation 217Hz	0.2	0.3	9
5500						
5785						

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.

Proximity magnetic fields	IEC 61000-4-39 test level	Compliance level	Electromagnetic environment – guidance
Proximity magnetic fields	134.2kHz Pulse modulation 2.1 kHz	65A/m	Power frequency magnetic field should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Proximity magnetic fields	13.56MHz Pulse modulation 50 kHz	7.5A/m	



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.
3. 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.
4. If the use location is near (e.g. less than 1.5 km from) AM, FM or TV broadcast antennas, before using this equipment, it should be observed to verify that it is operating normally to assure that the equipment remains safe with regard to electromagnetic disturbances throughout the expected service life.

13.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.



those parts of the equipment that shall not be serviced or maintained while in use with a PATIENT:

- Handpiece
- Cartridge nut
- Silver tube
- Bending Tool

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

All rights of modifying the product are reserved to the manufacturer without further notice. The pictures are only for reference. The final interpretation rights belong to CHANGZHOU SIFARY MEDICAL TECHNOLOGY CO., LTD. The industrial design, inner structure, etc, have claimed for several patents by SIFARY, any copy or fake product must take legal responsibilities.



Changzhou Sifary Medical Technology Co., Ltd.

Add: No. 26 Yandanghe Road, Xinbei District, 213000 Changzhou, Jiangsu,
China

Tel: +86-0519-85962691

Fax: +86-0519-85962691

Email: info@sifary.com

Web: www.sifary.com

EU	REP
-----------	------------

Caretechion GmbH

Tel: +49 211 2398 900

Add: Niederrheinstr. 71, 40474 Düsseldorf, Germany

Email: info@caretechion.de

i

All rights reserved.

iii