REFINE

Instruction Manual for Curing Light

Please read this manual before operating

Guilin Refine Medical Instrument Co., LTD.

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content

1 Product introduction 4
2 Model and technical parameters 6
3 Installation and demounting 8
4 Operation 9
5 Cleaning, disinfecting and sterilizing..... 10
6 Transportation, storage and maintenance 11
7 Troubleshooting 12
8 Environmental protection 14
9 Statement 14
10 EMC-Declaration of conformity..... 14
Attachment. Reprocessing instructions of cleaning, disinfecting and sterilizing 20

⚠Safety Precautions

⚠**WARNING:** If you neglect these safety precautions, you may cause personal injury such as electric shock, fire or damage to the product.

1. Use a separate, grounded power outlet. Never use wet hands to unplug the power cord.
2. Please do not use other than the specified voltage to recharge the battery.
3. Please recharge the battery at least 4 hours before first time usage.
4. It is forbidden to touch the charging connector with metal or other conductor, to avoiding damage the circuit of charge or the battery.
5. It is forbidden to extrude, shake or rock the battery. The Lithium battery is forbidden to be in short-circuit situation and it is forbidden to put the battery with metal or other conductors.
6. Please recharge the battery in cool and ventilated room.
7. It is forbidden to self-taking-apart the battery, in order not to result in short-circuit or leakage.
8. Keep the Curing Light clean before and after operation. The optical fiber must be sterilized before each treatment.
9. During the operation, the light should be aimed straightly at the composite resin to ensure the effect of solidification.

⚠**WARNING:** Avoid aiming at eyes directly.

10. Don't knock or rub the Curing Light.
11. This product is intended for use in hospitals and dental clinics only. The user must be professionally trained and qualified dentists.
12. Only the original pedestal charger, adapter and Lithium battery could be used, because other brand pedestal charger, adapter and Lithium battery are likely to damage the circuit.
13. If you don't use this equipment for a long time, please take the battery out and preserve separately.

14. As a professional manufacturer of medical instruments, we are only responsible for the safety on the following conditions:

• The maintenance, repair and modification are made by the manufacturer or the authorized dealer.

• The changed components are original of our company and operated correctly according to instruction manual.

⚠ **WARNING:** No modification of this equipment is allowed.

⚠ **WARNING:** If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of equipment.

⚠ **WARNING:** If the curing light works for 40s continously,the temperature of the top of optical fiber may reach 56 °C.

⚠ **WARNING:** Do not modify this equipment without authorization of the manufacturer.

⚠ Contraindication :

The heart disease patient, pregnant woman, children and the person who are allergic to blue light should be cautious to use this equipment.

Symbol instruction

Symbol	Instruction	Symbol	Instruction
	Warning, Caution and Important! Check the Instruction Manual		Consult the accompanying documents
	Date of manufacture		Manufacturer
	According to the type of protection against electric shock: CLASS II EQUIPMENT		According to the degree of protection against electric shock:Type B applied part
	Screw inside/ outside		Used indoor only
	Recovery		Keep dry
	Handle with care		Atmospheric pressure for storage
	Temperature limitation for storage		Humidity limitation for storage
	Appliance compliance WEEE directive, Dispose as required by the law.		CE Mark
EC REP	Authorised Representative in the EUROPEAN COMMUNITY		

1 Product introduction

The product suppose to be used in hospital and dental clinic, should be used by trained qualified dentist. This Curing Light is used for the principle of ray radiation to solidify the light-sensitive resin by shooting at it in a short time, it is used to restore teeth and solidify material for whitening teeth.

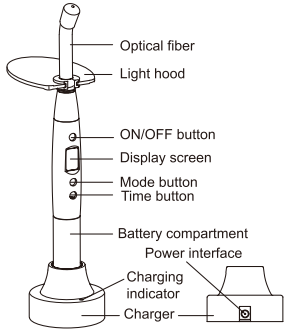


Figure 1-A MaxCure5

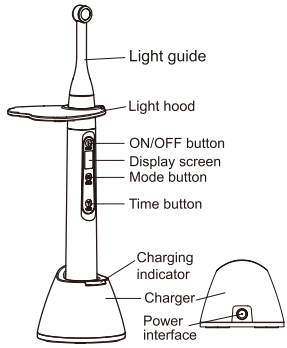
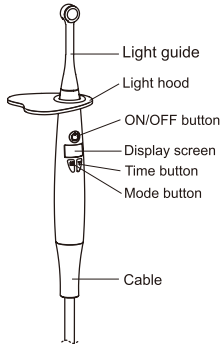
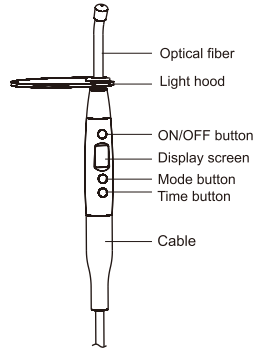


Figure 1-B MaxCure9





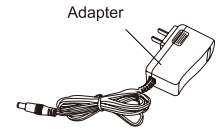


Figure 1-C MaxCureG Figure 1-D MaxCureH Figure 2 Adapter

Note: The button labeled 'Time' indicates the time setting, and the button labeled 'Mode' indicates the mode setting.

Safety classification	Working condition
1. Protection type against electrical shock: Class II 2. Protection degree against electrical shock: Type B 3. Protection against harmful ingress of water or particular matter: ordinary equipment (IPX0), can't be waterproof. 4. operation mode: short time run equipment. 5. Safety in the presence of flammable anesthetic mixture with air, oxygen or nitrous oxide: not suitable under this condition.	a) Environment temperature: 5°C-+40°C b) Relative humidity: 30%-75% c) Atmosphere pressure: 70kPa-106kPa

2 Model and technical parameters

Table 1: Technical Parameters of table-top models

Parameters	MaxCure5	MaxCure9
Power supply (Rechargeable Lithium battery)	Battery model: ICR18650 Battery voltage and capacity: 3.6V/2600mAh	Battery model: ICR18650 Battery voltage and capacity: 3.6V/2600mAh
Power supply (Adapter)	Input : 100-240VAC, 50Hz/60Hz Output: 5VDC/1A	Input : 100-240VAC, 50Hz/60Hz Output: 5VDC/1A
Applied part	optical fiber	Light guide
Light Intensity	1000mW/cm^2 - 1800mW/cm^2	1000mW/cm^2 - 2500mW/cm^2
Modes setting	TURBO mode: Display P1, Illumination 1600mW/cm^2 - 1800mW/cm^2 NORMAL mode: Display P2, Illumination 1000mW/cm^2 - 1200mW/cm^2	TURBO mode: Display P1, Light Intensity 2300mW/cm^2 - 2500mW/cm^2 NORMAL mode: Display P2, Illumination 1000mW/cm^2 - 1200mW/cm^2
Time setting	TURBO mode: 3S, 5S NORMAL mode: 5S, 10S, 15S, 20S Lightly press the time button to choose the solidification time.	TURBO mode: 1S, 3S NORMAL mode: 5S, 10S, 15S, 20S Lightly press the time button to choose the solidification time.
Dimensions	Φ25mm*250mm	Φ26mm×255mm

Parameters	MaxCure5	MaxCure9
Net weight	152g	144g
Light source	a) 5W high power blue LED b) Wave length: 420nm-480nm	a) 5W high power blue LED b) Wave length: 385nm-515nm
Consumption power	≤5W	≤5W
Composed mainly	main unit, charger, optical fiber, light hood, LED lamp, battery and power adapter.	main unit, charger, light hood, LED lamp, battery and power adapter.

Table 2: Technical Parameters of built-in models

Parameters	MaxCureG	MaxCureH
Power supply	Input : 24VAC, 50Hz/60Hz	Input : 24VAC, 50Hz/60Hz
Light Intensity	1000mW/cm^2 - 2500mW/cm^2	1000mW/cm^2 - 1800mW/cm^2
Applied part	Light guide	Optical fiber
Modes setting	**TURBO mode**: Display P1, Light Intensity 2300mW/cm^2 - 2500mW/cm^2 **NORMAL mode**: Display P2, Illumination 1000mW/cm^2 - 1200mW/cm^2	**TURBO mode**: Display P1, Illumination 1600mW/cm^2 - 1800mW/cm^2 **NORMAL mode**: Display P2, Illumination 1000mW/cm^2 - 1200mW/cm^2

Parameters	MaxCureG	MaxCureH
Time setting	**TURBO mode**: 1S, 3S **NORMAL mode**: 5S, 10S, 15S, 20S Lightly press the time button to choose the solidification time.	**TURBO mode**: 3S, 5S **NORMAL mode**: 5S, 10S, 15S, 20S Lightly press the time button to choose the solidification time.
Dimensions	Φ25mm*275mm	Φ25mm*265mm
Net weight	96g	159g
Light source	a) 5W high power blue LED b) Wave length: 385nm-515nm	a) 5W high power blue LED b) Wave length: 420nm-480nm
Consumption power	≤5W	≤5W
Composed mainly	main unit, LED lamp, light hood, cable.	main unit, optical fiber, light hood, LED lamp, cable.

3 Installation and demounting

3.1 Installation of the table-top models

a) Take off the red cap from the optical fiber and then insert the metal part into the front of Curing Light, make sure to screw the fiber to the end. To install the light hood on the top of the optical fiber. (The models with optical fiber)

b) To install the light hood on the top of the optical fiber.

c) For dismantlement, taking the instruction of istallment above reversely.

d) When finishing using or when the battery needs to be charged, connect the plug of the adapter into

the100-240VAC power supply. Then connect the output plug of the adapter to the input plug of the pedestal, and then the indicator turn to white (the MaxCure5 indicator turn to green), that means the pedestal is standby. Put the main unit to the charging point of the pedestal, the indicator turn to blue (the MaxCure5 indicator turn to yellow) , and the curing lights starts charging. When charging finished the indicator turn to white (the MaxCure5 indicator turn to green).

3.2 Installation of the built-in models

a) Connect the Curing Light power supply line with the power (24VAC) of dental unit. Tight the nylon thread to the fixation of the dental unit, then it will be available for operation.

Notice:When installing the Curing Light, be sure the power is cut off. The two power wire should be a little longer than the nylon thread to keep the power wire safe.

b) Take off the red cap from the optical fiber and insert the metal part into the front of the built-in Curing Light (Make sure to screw the fiber to the end by rotation).

c) Install the light hood as showed in picture 1.

d) Uninstall the Curing Light, just reverse the procedure above.

4 Operation

4.1 Modes setting: Lightly press the mode key to change the running modes. The Curing Light will shine the diffrent Illuminated blue light.The available modes see the **Technical Parameters table**.

4.2 Time setting: Lightly press the time button to choose the solidification time. The available time setting see the **Technical Parameters table.**

4.3 During the operation, aim blue light at the position needing solidification. Press the power button "ON/OFF" switch, a "beep" sound will appear, the Curing Light starts to work under the selected mode. Then it

counts down to "0" second to end the solidification.
4.4 During operation, the blue light can be stopped by press the power button "ON/OFF" at any time.
4.5 Low power detect circuit is fixed inside of the main unit, when low power is detected, the indicator of the main unit will wink, please charge in time.
4.6 After the operation, please clean the fiber with calico in order not to affect the light intensity.
4.7 This equipment will turn off automatically if no any action within 2 minutes, turn it on by press "ON/OFF" button.
4.8 The depth of solidification of composite is no less than 4mm per 10 seconds.
4.9 The Curing Light is equipped with over-heat protection system. It can continuously work 200s, For example, continuously operate the curing light for 10 times under 20s working mode, then it will come into over-heat protection status. And only after 2 minutes sleep, it can restart working 200s continuously.

5 Cleaning, disinfecting and sterilizing

5.1 Please conform to the recommendations of the manual "Reprocessing Instructions of Cleaning, Disinfecting And Sterilizing" delivered with your product regarding the procedure of cleaning, disinfecting, sterilizing and packing of the components. Follow present-day regulations enforced in the country about reprocessing. The use of scouring powder or an abrasive sponge will damage its surface.
5.2 The optical fiber can be sterilized. The light hood, LED lamp, battery and power adapter cannot be sterilized.

Notice:

a) Clean in the handpiece (detachable) with compressed air before sterilization.
b) Be sure that the optical fiber has been unscrewed from the handpiece and it cannot be sterilized with others.

c) Please notice whether the outer of the optical fiber is damaged during the treatment and sterilization. Change a new one once it is damaged or worn excessively.
d) Don’t smear any protective oil on the surface of optical fiber.

6 Transportation, storage and maintenance

6.1 Transportation

6.1.1 Excessive impact and shake should be prevented in the transportation. Lay it carefully and lightly and don’t invert it.
6.1.2 Don’t put it together with dangerous goods during transportation.
6.1.3 Avoid solarization and getting wet in rain or snow during transportation.

6.2 Storage

6.2.1 Don’t store the machine together with the articles that is combustible, poisonous, caustic, or explosive.
6.2.2 This equipment should be stored in a room where the relative humidity is 10%-93%, atmospheric pressure is 70kPa-106kPa, and the temperature is -20°C-+40°C.

6.3 Maintenance

6.3.1 The equipment should be handled carefully and lightly. Be sure that it is far from the vibration, and installed or kept in a cool, dry and ventilated place.
6.3.2 Please turn off the electrical source if not use it, if not use for a long time, please make the machine get through to the power once 3 months for five minutes.

7 Troubleshooting

Models Type	Faulty	Possible cause	Solutions
Built-in models	Non-indication Non-act.	1. The LED is not connected well with the power. 2. The power is off.	1. Check the connection of the LED and the power. 2. Make sure the power is on.
	Light intensity insufficient.	1. Optical fiber isn't inserted well to the bottom. 2. The optical fiber has cracked. 3. There is resin remain on the surface of the optical fiber.	1. Install the optical fiber well. 2. Change the optical fiber. 3. Remove the resin.

Models Type	Faulty	Possible cause	Solutions
Table-top models	No indication, no response.	1. Battery is out of power. 2. Faulty of battery. 3. The main unit battery protection system works.	1. Charge the equipment/Change a new battery. 2. Change a new battery. 3. Place the main unit into the socket on the charger for activation.
	Wink shown on the screen.	Low power.	Reconnect the charger.
	Light intensity is weak.	1. The optical fiber is not installed well. 2. There is crevice on the optical fiber. 3. There is resin on the tip of the optical fiber.	1. Reinstall the optical fiber. 2. Change a new optical fiber. 3. Clear the resin.
	The equipment is not charging when the adapter is connected.	1. The adapter is not connected well. 2. Faulty of adapter or incompatible. 3. The charging point is impurity.	1. Reconnect. 2. Change the adapter. 3. Cleaned by the alcohol.
	Effective duration of the battery become short.	The capacity of the battery decreased.	Change a new battery.
	The mode indicator twinkles when charging.	1. Low voltage. 2. Short-circuit of the battery.	1. Back to normal after 15 minuets charging. 2. Change a new battery.

If such handlings are completed, the equipment still cannot work normally, please contact with the local dealer or the manufacturer.

8 Environmental protection

Please dispose according to the local laws.

9 Statement

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 GUILIN REFINE MEDICAL INSTRUMENT CO., LTD. The industrial design, inner structure, etc, have claimed for several patents by REFINE, any copy or fake product must take legal responsibilities.

10 EMC-Declaration of conformity

The device has been tested and homologated in accordance with EN 60601-1-2 for EMC. This does not guarantee in any way that this device will not be effected by electromagnetic interference. Avoid using the device in high electromagnetic environment.

Guidance and manufacturer's declaration - electromagnetic emissions		
The models Curing Light are intended for use in the electromagnetic environment specified below. The customer or the user of the models Curing Light should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The models Curing Light 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 emissions CISPR11	Class B	The models Curing Light are suitable for used in domestic establishment and in establishment directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Guidance & Declaration — electromagnetic immunity			
The models Curing Light are intended for use in the electromagnetic environment specified below. The customer or the user of the models Curing Light 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 transient/ burst IEC 61000-4-4	±2kV for power supply lines ±1 kV for Input/output lines	±2kV for power supply lines ±1kV for interconnecting cable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line to line ±2 kV line to earth	±1 kV line to line	Mains power quality should be that of a typical commercial or hospital environment.

Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11.	<5 % UT (>95% dip in UT.) for 0.5 cycle 40 % UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95 % dip in UT) for 5 sec	<5 % UT (>95% dip in UT.) for 0.5 cycle 40 % UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95 % dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the models Curing Light require continued operation during power mains interruptions, it is recommended that the models Curing Light be powered from an uninterruptible 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 UT is the a.c. mains voltage prior to application of the test level.			

Guidance & Declaration - Electromagnetic immunity			
The models Curing Light are intended for use in the electromagnetic environment specified below. The customer or the user of the models Curing Light 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 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the models Curing Light, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=[3,5/V1]\times P^{1/2}$ $d=1.2\times P^{1/2}$ 80 MHz to 800 MHz $d=2.3\times P^{1/2}$ 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: 
NOTE 1 At 80 MHz end 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 models Curing Light are used exceeds the applicable RF compliance level above, the model Curing Light should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the models Curing Light.
[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

Recommended separation distances between portable and mobile RF communications equipment and the models Curing Light

The models Curing Light are intended for use in electromagnetic environment in which radiated RF disturbances is controlled. The customer or the user of the models Curing Light can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the models Curing Light are recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150kHz to 80MHz d=1.2×P1/2	80MHz to 800MHz d=1.2×P1/2	800MHz to 2.5GHz d=2.3×P1/2
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) accordable to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz. the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Attachment. Reprocessing instructions of cleaning, disinfecting and sterilizing

1. BEGINNING WORK!

1.1 Please read these operating instructions carefully as they explain all the most important details and procedures. Please pay special attention to the safety precautions. Always keep this instruction close at hand.

1.2 To prevent injury to people and damage to property, please heed the corresponding directives.

1.3 The instructions in this manual are only applicable to the equipment which it was delivered with.

2. INTRODUCTION

2.1 These reprocessing instructions provide instructions for cleaning, disinfection, sterilization and packaging of manufacturer reusable products intended to be reprocessed in medical facilities.

2.2 The goal of reprocessing reusable products is to reduce bioburden and to achieve sterility of those products in order to eliminate the risk of product reuse related infection. Decisions regarding cleaning, disinfecting or sterilizing manufacturer's medical and dental instruments are based on the potential risk of infection associated with their use.

2.3 It is recommended to use steam sterilization.

2.4 Remember that sterilization or high-level disinfection cannot be achieved unless the elements of the assembly are cleaned first.

2.5 If you find that the reprocessing instructions from the manufacturer seem to be inadequate, please inform manufacturer about those inadequacies.

2.6 We encourage you to report adverse events related to device reprocessing. Report such events directly to manufacturer.

3. REPROCESSING - INSTRUCTIONS FOR REUSABLE PRODUCTS

The instructions are binding for the reprocessing of all reusable products (Here after called "products") of manufacturer. When necessary, additional product-specific instructions are included with the product to provide additional information.

Important: Before use, carefully read the operating instructions of the manufacturer instrument and devices with which the product will be used.

Reusable products must be cleaned and sterilized prior to first use. They must be replaced after the number of operations specified by the manufacturer. Disposable products (single use) cannot be reused.

4. PREPARATION - Basic principles

4.1 It is only possible to carry out effective sterilization after the completion of effective cleaning and disinfection. Please ensure that, as part of your responsibility for the sterility of products during use, only sufficiently validated equipment and product-specific procedures are used for

cleaning/disinfection and sterilization, and that the validated parameters are adhered to during every cycle.
4.2 Please also observe the applicable legal requirements in your country as well as the hygiene regulations of the hospital or clinic. This applies especially with regard to the additional requirements for the inactivation of prions.

5. POST-OPERATIVE TREATMENT

The post-operative treatment must be carried out immediately, no later than 30 minutes after the completion of the operation. Additional information, while necessary, is provided in the respective product-specific usage instructions.

Steps:

1.Rinse away any surface soiling on the product with distilled deionized water or with a cleaning agent.
2.Rinse through all lumina (E.g. irrigation and aspiration connection) at least 3 times in the normal direction of flow (no back rinsing) using a disposable syringe (min. volume 50 ml) filled with distilled/deionized water applied to the back nozzle.
3.An aldehyde-free cleaning and disinfection solution that is compatible with the products may also be used as an alternative rinsing solution. In such cases, it is necessary to rinse thoroughly afterwards at least 3 times with distilled, or deionized water.

6. CLEANING/DISINFECTION:

6.1 MECHANICAL REPROCESSING

Disinfection must be performed no later than 2 hours after the cleaning phase.
A machine cleaning and disinfection method should always be used for cleaning / disinfection because of the increased effectiveness of this method.

6.2 MECHANICAL CLEANING AND DISINFECTION

6.2.1 Thermal disinfection should be used if this function is available on your disinfector. Use if possible a disinfecting cycle compliant with the standard EN ISO 15883.
6.2.2 Note that there is a risk of disinfectant residue on products when using chemical disinfectants.
6.2.3 Ensure the following criteria are met when selecting a disinfector system:
•Disinfector is proven effective through testing (E.g. FDA approved or CE marked / EN ISO 15883 compliant).
•Disinfector has suitable baskets to hold small fragile products and has rinsing connections for the attachment to product lumina.
•The cleaning program is suitable for products to be processed and the rinsing cycle is sufficient.
•Only low microbe count (<10 cfu/ml) distilled or deionized water is used for all rinsing steps. (E.g. Aqua purificata, as per the specifications of Pharm. Eur. or USP).
•Air used for drying is HEPA filtered.
•Disinfector is serviced and checked on a regular basis.

6.2.4 Ensure the following criteria are met when selecting a cleaning and disinfection agent:
•Chemicals are compatible with products.
•With non-thermal disinfection, a suitable disinfectant with tested effectiveness (E.g. FDA approved or CE marked), that is compatible with the cleaning agent, must be used.

⚠ **Concentrations and contact times specified by the manufacturer of the cleaning and disinfection agent must be followed. Only freshly prepared solutions may be used.**

6.2.5 Steps for mechanical cleaning and disinfection with a disinfector
1) Load the WD with the instruments on the tray and start the WD with a full load. Run the cleaning cycle of the "surgical instrument" programme in accordance with the manufacturer's instructions.
Instrument cleaning program:
• pre-wash (5 minutes, ambient temperature water)
• cleaning (5 minutes, 0.5% neutral pH detergent, 40℃)
• rinse I (1 minute, ambient temperature water)
• rinse II (1 minute,ambient temperature water)
• disinfection (2.5 minutes, pure water 93℃)
2) Immediately after the cleaning cycle, interrupt the program and unload the samples.
3) After cleaning in the WD, examine the instruments visually.
4) Carefully place the products in the disinfection basket. Fastening of the products is only permissible if they are freely moveable in the fixture. The products are not permitted to make contact with one another.
5) Using a suitable rinsing adaptor, connect the product lumina to the rinsing connections of the disinfector.
6) Start the program.
7) Remove the products from the disinfector and start the inspection (see section Inspection and maintenance) after the program ends.
8) Wrap the products directly following disinfection and drying (see section Packaging and sterilization). If necessary, repeat drying of the product in a clean place.

7. INSPECTION AND MAINTENANCE

If stains are still visible on the product after cleaning/disinfection, the entire cleaning/disinfection procedure must be repeated. Products with visible damage, chip/flake loss, corrosion or bent out of shape must be disposed of (no further use is permissible).

8. PACKAGING AND STERILIZATION

⚠ **Do not exceed the maximum number of sterilization cycles.**

Only cleaned and disinfected products are permitted to be sterilized. Prior to sterilization, the products need to be placed in a suitable sterilization container:
•Compliant with EN ISO 11607,
•Resistant to 138°C, with adequate steam permeability,

•Maintained on a regular basis.
If double, single-use sterilization packaging (double bag) is to be used, this must also comply with EN ISO 11607 and be suitable for steam sterilization (temperature resistant to 138°C with adequate steam permeability).
Use only the following listed steam sterilization procedures for sterilization; other sterilization procedures are not permissible:
•Fractional pre-vacuum procedure (steam sterilization with repetitive pre-vacuum.)
•Steam sterilizer in accordance with EN 13060 or EN 285 validated in compliance with EN IS0 17665,
•Maximum sterilization temperature 138°C,
•Sterilization time at least 3 min. at 134°C (fractional pre-vacuum procedure),
•Sterilization at 134°C for a maximum of 20 minutes is permissible.

⚠ **The hot-air sterilization and radio-sterilization procedure may not be used (as it causes the destruction of products).**

⚠ **The manufacturer assumes no responsibility for the use of other sterilization procedures (E.g. ethylene oxide, formaldehyde and low temperature plasma sterilization). In such cases, please observe the respective valid standards (EN IS0 14937/ANSI AAMI IS0 14937 or the procedure-specific standard) and verify the suitability and effectiveness in principle of the procedure (if necessary, including investigations on sterilizing agent residue), taking into account the specific product geometry as part of the validation.**

9. SERVICE LIFE

The products have been designed for a large number of sterilization cycles. The materials used in their manufacture were selected accordingly. However with every renewed preparation for use, thermal and chemical stresses will result in aging of the products.
If the number of permissible re-sterilization cycles is restricted, this will be pointed out in the product specific instructions.
The use of ultrasound baths and strong cleaning and disinfection fluids (alkaling pH>9 or acid pH<5) can reduce the life span of products. The manufacturer accepts no liability in such cases.
The products may not be exposed to temperatures above 138°C.

Guilin Refine Medical Instrument Co., Ltd.
No.8-3, Information Industrial Park, High-Tech Zone,
Qixing District, Guilin, Guangxi, 541004, P.R. China
Tel: +86-773-7796686 Email:refine@refine-med.com
Website: http://www.refine-med.com

EC REP MedNet EC-REP GmbH
Borkstrasse 10 · 48163 Muenster · Germany

After service and Warranty Instruction

1 Period validity: 2 year's free repair for the main unit, charger and adapter, 1 year's free repair for lithum battery. Lifetime maintanence.

2 Range of warranty: Within the warranty period of validity, we are responsible for any troubles caused by quality problems or products technique and structure.

3 The followings are beyond our warranty:

1) The damage caused by disobeying the operation instruction or lack of the needed condition.

2) The damage caused by unsuitable operation or disassembly without authorization.

3) The damage caused by unadvisable transportation or preservation.

4) There isn’t the seal of distributor or the warranty card isn’t filled in completed.

After service card

Name of Customer			
Address			
Post Code		Tel	
E-mail			
Purchase Date		Production Date	
Distributor			
Model		Product No.	

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