Model

RJ-MP
EM 100

RJ-PS
ES-1011 Oscillating Saw ES-3032 Sternum Saw ES-3031Reciprocating Saw
ES-2011 Micro Oscillating Saw

TEL 0553-2673688

Registrant/manufacturer name：Wuhu Ruijin Medical Instrument & Device Co., Ltd.
Registrant's Residence/ Production Address: 33rd , East Wanchun Road, Wuhu Economic and Technological Development Zone, Wuhu , Anhui Province, P.R.C.
After-sales service unit: Wuhu Ruijin Medical Instrument & Device Co., Ltd
TEL: 0553-2673688 FAX: 0553-2672513 Zip Code: 241000
Production License: W.X.Z.Z.XU NO.: 20160013
Medical Device Registration Certificate: W.X.Z.Z. No.: 20162040284

Revised date: Apr, 2022
Version/Times: B/3

MEDICAL ELECTRIC SAW DRILL

Operating Manual E Series

RJ-010002-Rev:03

Please read this manual carefully before use and keep it properly

Dear user

Thank you for using this product! This manual contains important contents that must be understood for safe and proper use of the product.

The instruction manual is a part of the product. Therefore, this manual should be placed in a proper position for easy reference at any time for the whole lifetime.The product must be operated by trained personnel with relevant knowledge and experience. All personnel must read this instruction carefully before using this product.

This manual shall be transmitted to subsequent owners or users of the product.Any duplication, photogrammetry, digital post-processing or duplication is prohibited without consent of Wuhu Ruijin Medical Instrument & Device Co.,ltd.

This product is safe and reliable to use, except for the risk s arising from special factors like operated by non-professionals or used for other purposes,etc.Therefore, please follow strictly the following rules to avoid accidental use. The product must be operated by professionals.

Product maintenance must be carried out by professional technicians or skilled users of Wuhu Ruijin Medical Instrument & Device Co.,ltd and the authorized person.

If there are any operation problems not mentioned, please contact WuhuRuijin Medical Instrument & Device Co.,ltd.

Instructions are subject to change without prior notice.Please put the manual in a proper position for reference.

I.Product information

Product Name: Medical Electric Saw Drill

Product Model No.: RJ-MP RJ-PS

Product technical requirement No.: W.X.Z.Z No.:20162040284

II.Corporate information

Registrant/manufacturer name：Wuhu Ruijin Medical Instrument & Device Co., Ltd.
Registrant's Residence/ Production Address: 33rd , East Wanchun Road, Wuhu Economic and Technological Development Zone, Wuhu , Anhui Province, P.R.C.
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III.Main performance parameters

Sequence	Model No.:	Performance parameters
1	RJ-MP	Main performance parameters: Non-loading rotation speed or frequency of electricsaw and drill: i. Drill rotating speed 120rpm ii. Saw frequency: ⩾6000 times/min iii.Output power: ⩾50W iv. Temperature rise: the temperature rise of the shell is no more than 50°C after 5min of non-loading operation; v. Non-loading noise: drill saw non-loading noise ⩽75dB(A); vi. Electric saw & drill saw blades shall be heat treated and its hardness shall be no less than 30 HRC.
2	RJ-PS	

IV.The structural composition

This product is mainly composed of handpiece, drill components, saw components, accessories, battery and charger.

i.RJ—MP

(i).EM100

(ii).EM-300

ii.RJ—PS

V.The scope of application

Applied in bone drilling and cutting in orthopedic surgeries for medical organization.

VI.Contraindications, precautions, warnings and explanatory notes

i.Contraindications

NO

ii.Precautions

(i)Check whether the radial run-out of the bit is intact before use. The bit with large radial run-out cannot be used. Check the sharpness of the drill bit. The drill body should be fixed during drilling without loosening according to conventional surgical methods.

(ii).The drill bit must be firmly fixed well with drill chuck key to avoid accidents. Products and accessories should be placed in a dry place to prevent corrosion after use.

(iii).The battery shall not be disinfected by high temperature, high pressure or stay in the machine for a long time, take out battery after the operation.If power is cut off during the operation (the handpiece does not work), the backup battery should be replaced immediately.

(iv).If there is abnormal sound when using,stop using it immediately. Please contact with the manufacturer or distributor immediately and return the machine to the manufacturer for repairing.

(v).Charge the battery immediately after use. If the battery is not used, charge it every three months to prevent battery loss.

iii.Warning and suggestive notes

The medical electric drill saw is classified according to the protection of electronic equipment from shock and vibration. The motor belongs to B-type equipment of internal power supply, and the charger belongs to class II B-type ordinary equipment; The equipment shall not be used with a mixture of flammable anesthetic gas or carbon oxide; Sterilization must be carried out before use.

Supplementary external mark: ⚠ Working schedule: Short time operation
Each starup time shall not exceed 5min.

Marking pattern description: B-type equipment

Rotation mark: **F**: Forward **R**: Reverse **S**: Stop ◀ Operation

Battery cover marking: Unlock Lock

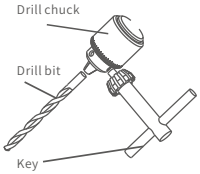
Recycling marks for electronic products at the end of their life:

VII.Installation and dis-assembly

This product is professional medical device, the installation and dis-assembly must be performed by medical personnel with appropriate technology or with appropriate professional training.

i.Installation and dis-assembly of drill bits

(i).Loosen the chuck by turning counterclockwise with the drill chuck key;
(ii). Insert the prepared bit into the three-jaw hole
(iii).Turn the drill chuck key clockwise and tighten it vigorously.
(vi).Conversely, the drill bit can be removed



ii.Installation and removal of oscillating saw blade

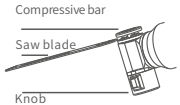
(i). Turn the knob counterclockwise to lift the pressure bar;

(ii). Insert the blade into the interface along the guide direction. Align the seven holes of the blade with the seven lugs of the product. Press down gently to make the lugs pass through the saw blades holes.

(iii).Turn the knob clockwise and pull down the pressure bar Locking saw blade;

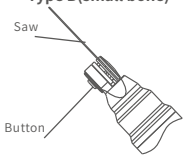
(vi).Conversely, the saw blade can be removed.

Type A



Type B(small bone)

Press the button first, then put the saw blade into the interface of the saw blade, align the position, the saw blade hole falls into the circular column of the interface of the saw blade, then release the button to lock the saw blade.



iii.Installation and removal of sternal saw/reciprocating saw blade

(i).Hold the knob with one hand, apply force to the limit screw, and rotate the knob;

(ii). Pull the protective rack with the other hand, and the protective rack can be removed;

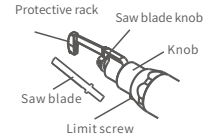
(iii).Rotate the saw blade knob;

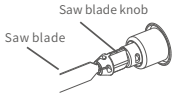
(iv).Aim the saw blade at the installation slot, loosen the saw blade knob, and then saw blades is installed well.

(v). Repeat the operation with serial number 1, insert the protection frame into the slot;

(vi).Release the knob, the protection frame is fixed, and the installation is completed;

(vii).Conversely, the saw blade can be removed.





iv.Installation and removal of cranial milling cutter

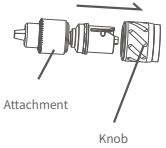
Type B

(i) .Align the assembly installation position with the handpiece,and pay attention to the phase position;

(ii). Turn the knob on the handpiece;

(iii).Release the knob after insertion, jam the drill or saw adapter and complete installation;

(iv).Converse to detach components.

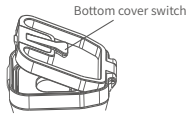


v.Opening and closing of the bottom cover

Type A

(i) .When opening the bottom cover, pull up the bottom cover;

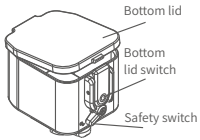
(ii). After installing the battery, press hard on the bottom cover until it reaches the bottom cover Close, then press the bottom cover switch firmly to ensure the bottom coverLocking.



Type B

(i).When opening the bottom lid, push the safety switch to the position and press the bottom lid switch to open the bottom lid.

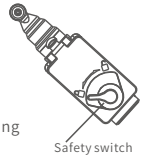
(ii). While closing the bottom lid, push the safety switch to the position ,press the bottom lid until switch hangs the bottom lid, and then push the safety switch to the position, then the bottom lid is closed.



Type C(small bone)

(i).When opening the bottom cover, turn the knob to the unlocked position and lift the bottom cover upwards.

(ii).When closing the bottom cover, put the bottom cover into the main unit, turn the knob to the unlocking position, press the bottom cover firmly, and turn the knob to the locking position to ensure that the bottom cover is locked.

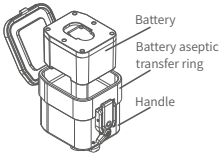


vi.Battery installation

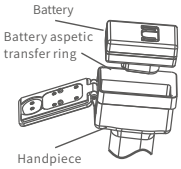
(i).The battery can not be directly connected with the handpiece to prevent pollution.

(ii).Before installing the battery, install the battery aseptic transfer ring onto the battery box, insert the battery into the battery compartment through the battery aseptic transfer ring, press it into place, remove transfer ring, and close the bottom cover.

Type A



Type B(small bone)



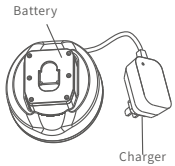
VIII.Operating instructions

This product must be disinfected before use and tested before use after disinfection.The method is: insert the corresponding battery for the handpiece, press the trigger gently, the motor shall rotate,switch forward and reverse, the motor work, or else, the handpiece has a problem, then please stop using immediately, contact the manufacturer or distributor to send product back to the manufacturer for maintenance.

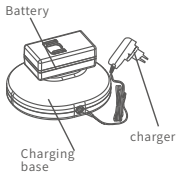
i.Battery charging

(i) .Plug the charger into the power supply, and the blue green light flashes alternately to indicate that the self-test is qualified and the charger enters the standby state;
(ii). Insert the battery into the charger base. The blue light is always on to indicate charging, the green light indicates full,and the blue light flashes to indicate an error.

Type A



Type B(small bone)

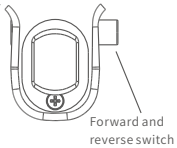


(i).Plug the DC port of the charger terminal into the DC port of the charging base, and insert the battery into the charging base to charge.

(ii).When the charger is connected to the power supply, the indicator is green. After inserting battery,the blue light indicates charging, and the green light shows fully charged.

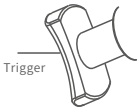
ii.Forward and reverse operation

(i) .When you need forward rotation, please adjust the knob mark to the corresponding F mark.
(ii). When you need reverse rotation, please adjust the knob mark to the corresponding R mark.
(iii).Turn the mark to postion S to show stop.



iii.Trigger operation

The adjustment of the speed is linear and depends on the extent of pressing the trigger. When turning on the trigger for the first time, you should lightly touch the trigger until it starts, and then press it slowly until it reaches the maximum speed. Quick release of trigger triggers the emergency stop function.



IX.Maintenance

This product is maintenance-free. It contains no parts that require maintenance by the user or manufacturer. However, the manufacturer recommends that the function and safety of the product be checked regularly by a professional or hospital technician.It must be checked once before each operation, and be recorded, analyzed and evaluated in time to ensure that the product is in good condition and guarantee the use quality.

X.Cleaning and sterilization

A.Cleaning: the protection of cleaning after use is same as sterilization, and the handpiece can be wiped clean with gauze soaked in water or alcohol and then store.

B.Disinfection: Product can be used only when passing inspection after disinfection and sterilization according to the hospital standards.

Note: Do not soak any part of the medical electric saw drill in liquid.

Recommended handpiece disinfection method

Disinfection method	Operating conditions and environment	Scope of application	Limitation
Moist heat sterilization	Sterilization conditions are generally are: 121°C*15min,121°C*30min or 116°C*40min	High temperature and humid product sterilization	1.High temperature 2.High humidity 3.It is easy to breed bacteria again when the product is wet

Commitment

i:This instrument has no parts that can be disassembled and repaired by non- professionals. If it fails, please contact the company's after- sales service department.

ii: If you need technical information about this medical electric drill, please write to us.。

XI.Transport and storage conditions

Transport and storage conditions	Ambient temperature range	-10°C～+40°C
	Relatively moderate range	⩽90%
	Atmospheric pressure range	500hPa～1060hPa
Equipment operating conditions	Ambient temperature range	5°C～40°C
	Relatively moderate range	⩽70%
	Atmospheric pressure range	860hPa～1060hPa
	Charger power	100-240V±10%；50/60Hz±1Hz
	Main power supply (DC)	7.4/14.8V±10%

Note: According to YY0904-2013 battery-powered bone tissue surgery equipment

Production date: Refer to product certificate
Service life: two years short-time running 1000 times

XII.Accessories list

Prepare standard configuration and accessories according to product model number and product customer need, such as such as saw blade, drill bits, battery aseptic transfer ring, drill chuck keys,etc.

Parts List				
No.	Name	Model No.	Quantity	Note
1	Handpiece	XXXX	1pcs	According to customer needs
2	Battery	XXXX	2pcs	According to the handpiece model
3	Aseptic Battery Housing (Excluding small bone)	XXXX	1pcs	According to the handpiece model
4	Charger	XXXX	1pcs	According to the handpiece model
5	Charger base		1pcs	According to the handpiece model
6	Manual		1pcs	
7	Certificate of conformity		1pcs	
8	Three certificates		1pcs	

XIII.Electromagnetic compatibility

Guidance and manufacturer´s declaration – electromagnetic emission

The RJ-MP(RJ-PS;RJ-PD) is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions GB4842	Group 1	The RJ-MP(RJ-PS;RJ-PD) 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 GB4842	Class A	The RJ-MP(RJ-PS;RJ-PD) is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions GB17625.1	Not applicable	
Voltage fluctuations flicker emissions GB17625.1	Not applicable	

Guidance and manufacturer´s declaration – electromagnetic immunity

The RJ-MP(RJ-PS;RJ-PD) is intended for use in the electromagnetic environment specified below. The customer or the usershould assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment -guidance
Electrostatic discharge GB/T 17626.2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 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 %.
Electrostatic transient / burst GB/T 17626.4	± 2 kV for power supply lines	± 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge GB/T 17626.5	± 1 kV wire to wire	± 1 kV wire to wire	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 GB/T 17626.11	0 % UT; 0,5 cycle g) At 0°, 45°, 90°, 135°, 180° 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycle	0 % UT; 0,5 cycle g) At 0°, 45°, 90°, 135°, 180° 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycle	Mains power quality should be that of a typical commercialor hospital environment.If the user of the RJ-MP (RJ-PS;RJ-PD) requires continued operation during power mains interruptions,it is recommended that the RJ-MP(RJ-PS;RJ-PD) be powered from an uninterruptible power supply or a battery.
Power frequency (50 Hz) magnetic field	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Guidance and manufacturer´s declaration – electromagnetic immunity

The RJ-MP(RJ-PS;RJ-PD) is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment -guidance
Conducted RF GB/T 17626.6	3 V(Effective value) 150 kHz to 80 MHz	3 V (Effective value)	Portable and mobile radio frequency communication equipment should not be used in any part of RJ-MP (RJ-PS, RJ-PD), including cables, than the recommended isolation distance. The distance should be calculated by the formula corresponding to the transmitter frequency. Recommended isolation distance d=1.2 d=1.2 80MHz~800MHz d=2.3 800MHz~2.5GHz Where: p-----According to the maximum output power of the transmitter provided by the transmitter manufacturer, in watts (w); d-----Recommended isolation distance, in meters (m) The field strength of the fixed RF transmitter is determined by surveying the electromagnetic field a, and in each frequency range b should be lower than the compliance level.Interference may occur near equipment marked with symbols as beside.
Radiated RF GB/T 17626.3	3 V(Effective value) 80 MHz to 2.5 GHz	3 V/m	

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

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

b 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 measuredfield strength in the location in which the RJ-MP(RJ-PS;RJ-PD) is used exceeds the applicable RF compliance level above, the RJ-MP (RJ-PS;RJ-PD) should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the RJ-MP(RJ-PS;RJ-PD).

c Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

Recommended isolation distance betweenportable and mobile video communication equipment and RJ-MP (RJ-PS, RJ-PD)

RJ-MP (RJ-PS, RJ-PD) is expected to be used in anelectromagnetic environment with controlled radio frequency radiation disturbance. According to the maximum rated output power of communication equipment, the purchaser or user can prevent electro magnetic waves by maintaining the minimum distance between portable and mobile radio frequency communication equipment (transmitter) and RJ-MP (RJ-PS, RJ-PD) as recommended below interference.

Interference test	IEC60601 test level	Coincidence level	Electromagnetic
Maximum rated output power of the transmitter	Corresponding to the isolation distance of the transmitter at different frequencies/m		
	150kHz～80MHz d=1. 2	80MHz～800MHz d=1. 2	800MHz～2.5GHz d=2.3
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 the maximum rated output power of the transmitter not listed in the above table, the recommended isolation distance d, in meters (m), can be determined by the formula in the corresponding transmitter frequency column, where P is the emission provided by the transmitter manufacturer The maximum rated output power of the machine, in watts (w).

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 from structures, objects and people.