



Reusable Electrode Surgical Instruments

(Coagulation Electrode)

Instructions for Use

222-51110 222-52120 222-50150 222-51220 222-52230 222-50250 222-51440 222-52540
222-52550 222-51610 999-015 999-030

STATEMENT

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- This product is operated under strict observation of this manual.
- This product is not damaged by human factors. Human factors refer to unintentional falling, intentional damaging, etc.

In the event that it becomes necessary to return a unit to Mindray, please contact the Mindray Service Department.

Please provide the model number, batch code, and a brief description of the reason for return. The customer is responsible for freight charges when this product is shipped to Mindray for service (including any relevant customs fees or other freight related charges).

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Intended Use

This device is intended to be used in laparoscopic operation. Probe to cauterize soft tissue, organ during the surgical procedures. The coagulation electrodes with suction can also aspirate the fluids from the abdomen. Reusable monopolar cord is designed to connect an electrosurgical device, such as monopolar forceps to a compatible electrosurgical generator.

Contraindications for Use

The instrument is not intended for use when endoscopic techniques are contraindicated.

Description

1. **Working parameter:** $\phi 5 \times 330\text{mm}$, $\phi 5 \times 450\text{mm}$;
2. **Specification of connector:** $\phi 4 \times 18.6\text{mm}$
3. **Rated voltage** of mono-polar surgical instrument: 3000V.

The instrument is shipped non-sterile. To prevent infection, this instrument must be cleaned and sterilized by the user prior to use.

WARNING

- During high frequency operation if operated improperly may cause unintended damage of tissue, gas embolism, low frequency leakage, influence other electronic equipment, etc. Follow all instructions for use required by the generator manufacturer. Consult medical literature or country specific regulations for specific techniques, complications and hazards prior to procedure.
- Verify the compatibility of parts from different manufacturers prior to conducting the procedure. And make sure the repeat peak voltage not exceed the rated voltage of the instrument.
- Ensure device grasping or cutting surfaces are fully visible prior to engaging the electrical current to avoid unwanted damage. Keep the working-end under full and unobstructed visualization during use.
- The instrument should be used cooperated with endoscope and the accessories in the laparoscopic operation.
- Endoscopic surgery should be performed only by physicians who are thoroughly trained in endoscopic techniques and failure modes, precautions and corrective actions in the event of failure.
- Connect bipolar accessories to the bipolar receptacle only and monopolar accessories to the monopolar receptacle only. Do not attempt to connect or interchange bipolar and monopolar accessories and receptacle connections. Improper connection of accessories may result in inadvertent accessory activation or other potentially hazardous conditions.
- The material of tip includes ceramics which is fragile. Do not knock or crash the tip in the operation and maintenance process.
- Do not use a damaged or faulty instrument. Check the instrument for bent, broken, cracked, worn, or separated parts prior to use.

CAUTION

- Do not use excessive force or in a manner not consistent with normal instrumentation use.
- The head of the monopolar electrocoagulation device contains fragile ceramic materials which should be gently handled during use and movement.

- During the operation, avoid the head of the monopolar electrocoagulation device from being flushing;

General Instruction for Use

1. Make sure the product has been cleaned and sterilized prior to the first use and after every subsequent use.
2. Inspect the instrument for overall condition and physical integrity. Do not use the instrument if any damage is noted.
3. Attach the monopolar cord to the connector end of the instrument.
4. Conduct the procedure using a standard endoscopic technique.

Clean, Sterilization and Disinfection

- Clean: We recommend using the ultrasonic cleaning method to clean.
- Disinfection: It is recommended to be disinfected by 2% alkaline glutaraldehyde. Please follow the instruction of disinfectant manufacturer.
- Sterilization: We recommend using the moist heat, the sterilization parameter listed below:

Sterilization Method	Product Category	Temperature	The Minimum Time	Pressure
Moist heat—Gravity Displacement Autoclave	Appliance	121℃	30 Min	102.9 Kpa
Moist heat—Pre Vacuum Process	Appliance	132~134℃	4 Min	205.8 Kpa

Storage conditions

- The instrument should be stored in controlled environment, protected from light, fire, rat and the insects. Keep the environment clean, well ventilated and without corrosive gases

Transportation conditions

- Temperature range: -20℃~50℃; relative humidity range: 10%~80%; atmospheric pressure: 500hpa-1060hpa.

Symbol Description

Table 1 Symbol Definitions

	Type BF applied part		Batch Code		Manufacturer
	Latex-free		Caution		Catalogue Number
	Refer to instruction manual/booklet		Humidity limitation		Keep Dry
	Keep away from sunlight		Fragile, handle with care		Stacking limit by mass
	Atmospheric pressure limitation		This way up		Temperature Limit
	Separate collection for electrical and electronic equipment		Unique Device Identification		Medical Device
	The product conforms to the requirements of the EC Directive MDD(93/42/EEC) on medical device		Authorized representative in the European Community		Trademark of manufacture, authorized by Shenzhen Mindray Bio-Medical Electronics Co., Ltd.

Table 2 Definitions of Safety Notes

Safety Notes	Meaning
	Read the statement below the symbol. The statement alerts you to an operating hazard that can cause personnel injury.
	Read the statement below the symbol. The statement alerts you to possible damage to the device or other property.