

CE Technical file of Yankauer Suction Handle ——Instructions for Use File No.: BST-CE-08-02-02 Revision: A/0 Effective Date: YYYY-MM-DD

CE2797

Instructions for use

[Product Name]

Yankauer Suction Handle

[Intended Use]

Yankauer Suction Handle is used to suction liquids or blood to provide clear surgical field during surgical procedures.

[Indications]

There is no specific disease or medical condition. It is only intended for the diseases or conditions that require removal of the blood or body liquids in combination with suction source and suction devices during a surgical procedure.

[Contraindications]

There is no absolute contraindication.

[Patient target group]

Patients who need liquids or blood suction during surgical procedures.

[Intended users]

Healthcare professionals.

[Use Method]

- 1) Open the package and take out the Yankauer Suction Handle.
- Connect the Yankauer Suction Handle to the suction connecting tube, suction drainage device and the suction source.
- 3) Ensure all connections are secure.
- 4) Turn on the suction source and test suction through the Yankauer Suction Handle prior to use.

[Warnings and Precautions]

- 1) The product has been sterilized by EO with validity for 5 years.
- 2) This product needs to be operated and used by healthcare professionals.
- 3) Check whether the package is complete. If the package is damaged, do not use it.
- 4) This product is for single use. Please destroy it after use, the destruction procedures shall be handled harmlessly by qualified or authorized institutions according to the local relevant regulations.
- 5) Please inform the manufacturer in case of any incidents related to the device occur and report to the competent authority of the Member State in which the incidents occurred, if applicable.

[Shelf-life]

Five years.

[Sterilization Method]

Ethylene oxide.

[Storage and Transport Conditions]

- 1) No heavy pressure, direct sunlight, rain or snow dipping, so as not to damage the device.
- 2) Handle with care during transport and avoid violent collision.
- The product should be far away fire, heat source and corrosive gas, and please pay attention to good ventilation.
- 4) Store in a cool and dry place, and ensure that the room is well ventilated, no corrosive gas, and relative humidity does not exceed 80%.

[Production Date]

See on the package.

[Symbol Explanation]

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		Manufacturer	ξz	Date of manufacture, Country of manufacture
	EC REP	Authorized representative in the European Community/ European Union	LOT	Batch code
		Use-by date		Do not use if package is damaged and consult instructions for use
	Ĩ	Consult instructions for use	\triangle	Caution
	STERGUZE	Do not resterilize	\otimes	Do not re-use
	\bigcirc	Single sterile barrier system	STERILEEO	Sterilized using ethylene oxide
	MD	Medical device	UDI	Unique device identifier
	C € 2797	CE Marking	REF	Catalogue number
		Keep away from sunlight	Ť	Keep dry
		Stacking layer limit	I	Fragile, handle with care

TUORen

[Manufacturer]

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