

——Instructions for Use File No.: BST-CE-08-02-02 Revision: A/2

Effective Date: 2024-06-18

### Instructions for use



#### [Product Name]

Yankauer Suction Handle

#### [Intended Use]

Yankauer Suction Handle is used to suction liquids or blood from operative site of the patient.

#### [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.

#### [Contraindications]

There is no absolute contraindication.

#### [Patient Target Group]

Patients who need suction liquids or blood from operative site.

#### [Intended Users]

Healthcare professionals.

#### [Clinical Benefits]

Yankauer Suction Handle can effectively suction liquids or blood from operative site of the patient, and the suction success rate is more than 95%.

#### [Side Effects]

Including, but not limited to: Tissue injury, bleeding, infection.

#### [Use Method]

- 1) Open the package and take out the Yankauer Suction Handle.
- 2) 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. Do not reuse, reprocess or resterilize. Reuse of the device poses a potential risk of infection, injury, and/or illness. (i.e. It may lead to contamination and/or limited functionality capability. Contamination and/or limited functionality of the device may lead to injury, illness of the patient).

- 5) This product comes into contact with blood or body liquids, which can be contaminated. Care should be taken in the handling and disposal of the device after use to prevent contamination. The disposal procedures shall be handled harmlessly by qualified or authorized institutions according to the local relevant regulations.
- 6) 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.

# [Clinical Lifetime] Less than 15s/time.

## [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.
- 3) 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]

	Manufacturer	CN	Date of manufacture, Country of manufacture
EC REP	Authorized representative in the European Community/ European Union		Do not use if package is damaged and consult instructions for use
53	Use-by date	LOT	Batch code
[]i	Consult instructions for use	$\triangle$	Caution
STEROUZE	Do not resterilize	(2)	Do not re-use
	Single sterile barrier system	STERILEEO	Sterilized using ethylene oxide



#### **CE Technical file of Yankauer Suction Handle**

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MD	Medical device	UDI	Unique device identifier
<b>C</b> € <sub>2797</sub>	CE Marking	REF	Catalogue number
漆	Keep away from sunlight	学	Keep dry
5	Stacking layer limit	Ī	Fragile, handle with care



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EC REP [EU Representative]

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[Issue date]

2024-06-18

[Latest revision]

A/2

