

CE Technical File Video Laryngoscope	File No:RD/S-204-0002
	Rev. No: 1.0

宁波新跃医疗科技股份有限公司 使用说明书

产品名称: Laryngoscope Blades
文件编号: RD/S-204-0002
文件版本: 1.0

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INSTRUCTIONS FOR USE OF
Laryngoscope Blades

[Product Name]

Laryngoscope Blades

[Model and Specification]

Product name	Model and specification	Compatible Xinwell brand video Laryngoscope	Smallest width of the channel (mm)
Laryngoscope Blades (138)	XY-204-A-138	XY-204-A1	13.2
Laryngoscope Blades (126)	XY-204-A-126		11.2
Laryngoscope Blades (114)	XY-204-A-114		8.6
Laryngoscope Blades (087)	XY-204-B-087	XY-204-B1	8.6

[Parts Description]

As is shown in Fig.1, the Laryngoscope Blade is the accessory of Xinwell brand video Laryngoscope, which is composed of clip, endotracheal tube (ETT) channel, stand channel and spatula. The whole device is made of PC.

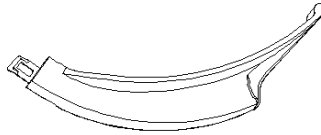


Fig. 1

[Product Description]

During clinical use, connect the Laryngoscope Blade (PC) with the stand of video Laryngoscope, then insert the blade to trachea for inspection of oropharynx and endotracheal intubation, insert ETT through ETT channel of endotracheal tube to perform artificial ventilation.

The device itself does not contain video laryngoscope and ETT, different size of blades are for different models of video Laryngoscope and populations. The device is put into market in ETO sterile state and for single use.

[Performance Index]

- I. For laryngoscope blade combined with video laryngoscope, the engagement of the blade onto any part of handle fitting shall be flexible and with no jam. The blade shall not disengage from the handle when a disengagement force of 50N is applied along the force axis.
- II. Ethylene oxide residue: The ethylene oxide residue shall be not more than 4mg/pc.
- III. Sterility: The device shall be sterile after sterilization with ethylene oxide.

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[Intended Use]

The product is used in combination with the video laryngoscope to pick up patients' epiglottis and expose the glottis, then guide medical staff to clear inspection of oropharynx and conduct accurate ETT intubation.

[Contraindication]

1. Severe airway trauma or obstruction that does not permit safe passage of ETT.
2. Cervical spine injury, in which the need for complete immobilization of the cervical spine makes endotracheal intubation difficult.

 Precaution:

1. Do not use the product if it is damaged or defective.
2. Make sure that excessive force is not placed on this product. Excessive force can result in failure.


 Warning

1. Do not use after expiry date.
2. Do not use if the package is open or damaged.
3. For single patient use only. Do not reuse, reprocess or re-sterilize. Reuse, reprocessing or re-sterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death.
4. Care should be taken during blade insertion.
5. Only trained medical professionals could use the device.

[Direction for use]

Step 1: Select appropriate size of laryngoscope blade and check the package if it is intact before use.

Step 2: Open the package and take out the laryngoscope blade, and connect it with the stand of video Laryngoscope, then verify the blade is lit properly.

Step 3: Press the power button “  ” of the laryngoscope and start to use.

Step 4 : After use, pull the clip open manually, and then exit it from the stand of laryngoscope.

[Maintenance and Storage]

1. Avoid hard pressure, direct sunlight and rain-snow exposure.
2. The device shall be stored in a non-corrosive gas, relative humidity NMT 80%, ambient temperature 0 °C to 40 °C and clean environment.

[Manufacture date and Expiry date]

Manufacture date: shown on the seal

Expiry date: shown on the seal

[Packaging marks]

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No	Symbol	Meaning	No	Symbol	Meaning
1		DATE OF MANUFACTURE	8		STERILIZED USING ETHYLENE OXIDE
2		DO NOT REUSE	9		CONSULT INSTRUCTIONS FOR USE
3		CAUTION	10		USE BY
4		MANUFACTURER	11		DO NOT USE IF PACKAGE IS DAMAGED
5		AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY	12		KEEP DRY
6		THE PRODUCT HAS PASSED CE CERTIFICATION	13		KEEP AWAY FROM SUNLIGHT
7		BATCH CODE	14		DO NOT RESTERILIZE
			15		TYPE BF APPLIED PART



The device is sterilized by ethylene oxide, and the shelf life is 2 years after sterilization.



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