

Tian Song®

Focusing Laryngoscope
Operating Manual

ZHEJIANG TIANSONG MEDICAL INSTRUMENT CO., LTD

- **Production License No., Product Registration No. and Implementation of standards of the enterprise**

- Zhejiang Food and Drug Administration Production No 20100200

- Zhejiang Food and Drug Administration No 2014 No 2220774

- This product has passed the Certification of Medical Devices Quality Management System which meets the demand of GB/T 19001-2016idt ISO 9001:2015 and YY/T 0287-2017idt ISO 13485:2016

Certification No: **04719Q10763R6M、04719Q10000879**

- This product has passed the Certification of EC Medical Devices Quality System which meets the demand of EN ISO 13485:2016

Certification No.: **CE—0197 SX 60123619 0001**

CE—0197 HD 60123618 0001

- **After-sales service**

- Repair guide: **After-sales service department of Zhejiang Tiansong Medical Instrument Co., Ltd requires the product which needs repairing should meet the demand of Warranty Statement.** We will repair the product and do an overall check as well. We provide free service if the product is before the limited period and paid service if it is out of the guarantee scope or exceeds the limited period.

- If you want to buy our products or have consultation, please contact with our Sales Department.

- Tel: +86(0)571-64241878、64241388; Fax: +86 (0)571-64241818

We have set up offices all over the provinces and cities in China to do service, try best to make sure the customers believe us, their contacts would be known if you phone our Sales Department.

- After-sales Tel: +86(0)571-64241168

- After-sales service company: Zhejiang Tiansong Medical Instrument Co., Ltd

Address: No. 168 Jianduan Road, Tonglu Economic & Technical Development Zone,
Hangzhou 311501, Zhejiang, China

Zip Code: 311501

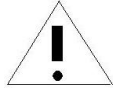
Website: www.zj-tiansong.com; www.chinaendoscope.cn

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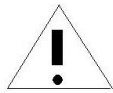
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Symbol description

In this manual we use the symbols as below:



Warning: mean the potential harm, if not avoid, may lead to die or the strong result.



Attention: mean the potential harm, if not avoid may lead middle or light result, also use as unsafe operation or potential harm.

Operator qualifies

The products operator should be the specialist or the medical affairs under the specialist' s supervision; they should be passed the fully special clinical focusing laryngoscope training. All the using method and the contraindication are only for reference.

1. Product usage

Focusing laryngoscope is mainly used with larynx instruments for larynx inspection and operation.

2. Main structure

Focusing laryngoscope is mainly composed of lens body, eyepiece casing, light pencil joint, focusing part and handle.

3. Main feature, specification and configuration

Item	No.	Name	Serial No.	Specification
laryngoscope	1	Focusing laryngoscope	D0103	70°
	2	Laryngoscope	D0101	90°
	3	Focusing laryngoscope	D0102	90°
	4	Laryngoscope	D0112	70°
	5	Laryngoscope	D0105	70°
	6	Focusing laryngoscope	D0110	70°
	7	laryngoscope	D0104.1	70°
	8	Light guide cable	T5012	1800mm

Note: The focusing laryngoscope can be operated with larynx instruments, please phone for details.

4. Applying field

Focusing laryngoscope is used with larynx instruments for larynx inspection and operation.

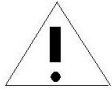
5. Using Method

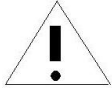
1. Lay the front point of disinfected laryngoscope into 40°C distilled water to prepare for use.

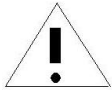
2. Insert fiber-optic light cable into the hole of light source and adjust light to the lowest degree. Then connect another end of fiber-optic light cable with laryngoscope. Finally turn on light source, if necessary, adjust light degree and focus the endoscope until the image is clear.

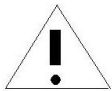
6. Attention

6.1 Warning and Attention

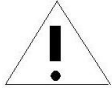
1)  **Attention:** Before using the focusing laryngoscope, please read the manual carefully and accessories manual.

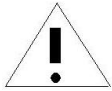
2)  **Warning:** The operator should be the certain qualification, and after the training and with the good operating skill. Before the operation, they should read the relative document include the technique, relative disease and the harm.

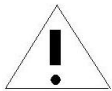
3)  **Warning:** If the sterilizing not totally, and the sterilizing liquid over the term or not sterilizing not follow the general requirement, all that case will possibly lead to intercross infection. Especially for the contagion and the cancer patient, must disinfect in time!

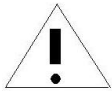
4)  **Attention:** Please check the inserted part of focusing laryngoscope if there are some roughened surface, acuity edge or


the prominence on the instrument.

- 5)  **Attention:** Focusing laryngoscope is the important guarantee of observation and diagnosis. Be careful when using. Always be mild, step by step, can't push by force, bump and bend.

- 6)  **Warning:** Whenever discovering the anomaly of focusing laryngoscope, he should immediately stop using it and extract slowly. It would be harmful to patients if operating with faulted focusing laryngoscope.

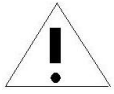
- 7)  **Warning:** Do not ever directly look at the cold light source, fiber optic cable or endoscope light, which would damage the eyes.

- 8)  **Attention:** Focusing laryngoscope is a kind of reusable medical devices. The long-term usage or improper maintenance will cause the aging of the reused focusing laryngoscope and the instruments. Please make sure every part of the focusing laryngoscope is safe and reliable before using.

- 9)  **Attention:** Before using the focusing laryngoscope, please check it if it is rough or has sharp outshoot. Once they were found, the operator should immediately stop using the focusing laryngoscope. Otherwise it will hurt the patient.

6.2 Cleaning, disinfection and sterilization

● Cleaning



Attention: The products are not disinfected and sterilized before the transportation. So that, before you first time use, you should do the cleaning, disinfecting and sterilizing as below.

- 1) Before disinfection, please discharge the cable from the focusing laryngoscope, and give the endoscope a thorough clean-up. Please separate the endoscope and other components when cleaning.
- 2) After using the focusing laryngoscope, it should be thoroughly washed with flowing water immediately to remove blood, mucus and other residue material. Then drying it.
- 3) About the focusing laryngoscope after drying, it should be soaked in a dedicated multi-enzyme cleaning lotion to prevent organic matter and protein coagulating, the soaking time of multi-enzyme lotion refers to the manual, and rinse under running water.
- 4) Focusing laryngoscope after washing, please dry it, to be

disinfected.

● Disinfection and sterilization

1> Ethylene oxide sterilization

——Mini ethylene oxide sterilizer relative condition

Ethylene oxide sterilizer gas concentration···600mg/L~800mg/L

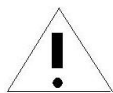
Temperature···········. 37℃ ~ 63℃

Relative humidity..... 40%–80%

Sterilizing time..... 1h–6h

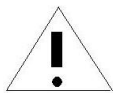
2> Glutaraldehyde sterilization

--- Put the cleaned and dry focusing laryngoscope to the 2% Glutaraldehyde vessel, cover and after 10 hours, take out by aseptic technique, clean it by aseptic water, then aseptic dry.



Note: The Glutaraldehyde must with the valid concentration the valid term, if not please change in time

3> The other sterilizing method under the ministry of health



Attention:

1) Openness concretion, hepatitis, AIDS patient or the pathogen carrier should use the special focusing laryngoscope, patient and the focusing laryngoscope should do the strictly sterilization, and the sterilizing vessel also should be separately strictly from the other patient. If using the special focusing laryngoscope is difficult, also should do the sterilizing or high-level disinfecting.

2) The focusing laryngoscope sterilized by the chemo sterilant, firstly should be cleaned by aseptic water to clean the rest disinfectant.

● Sterilization and disinfection of other parts

1) The surgical instruments used with focusing laryngoscope should be sterilized after cleaning.

2) Ethylene oxide sterilization can also be used, the methods and notes refer to the sterilization of focusing laryngoscope.

3) Sterilization by soaking in 2% glutaraldehyde for 10h, all parts should be soaked in disinfectant, all channels should be filled with disinfectant.

4) Fiber optic cable and other accessories can be disinfected by 75% alcohol cloth to wipe both sides, or adopt disposable sterile plastic cover to achieve the purpose of isolation disinfection, but the contact part should still be disinfected by alcohol.



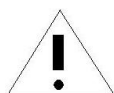
Note: All the clean, disinfecting and chemical method, steps and the technical parameters are only for reference. The detail should be accord with the operating manual.

7. Contraindication (Only for reference)

If the throat inspection is not clear, the laryngoscopy is very suitable for the following symptom.

1. Resection of vocal cord polyp
2. Resection of vocal nodules
3. Removal of hypopharynx or laryngeal foreign body
4. Resection of vocal cord cyst

8. Maintenance and Repair



Note: The products are cannot repaired by customer. Please do

not disassemble, modify or try to maintain, otherwise that will do harm to the patient or the operator, even damage the focusing laryngoscope.

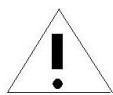
The focusing laryngoscope should be use carefully and lightly, avoid damaging the surface. Should be kept well.

1) When finish the operation, please clean in time and keep them well, even when you do the disinfecting, also should rudely, cannot disinfected by random. Disinfecting strictly follow the regulation avoid damagement.

2) If the focusing laryngoscope will be no use for long time, they should be put in the pneumatic drying place, checked every one to two weeks, be careful not to mould and rust.

3) Fiber optic cable cannot be over-bending, the radius of curvature shall be not less than 5cm, in order to avoid damage to optical fiber.

4) Focusing laryngoscope removal, storage should be handled with care, no bump, collision, extrusion, etc.



Note: Focusing laryngoscope is a kind of reusable medical devices

Using condition: Environment temperature: 10°C ~ 40°C

Relative humidity: 30%~75%

Air pressure: 700KPa~1060KPa

Storing condition: Environment temperature: -20°C ~ +60°C

Relative humidity: 10%~80%

Air pressure: 500KPa~1060KPa

Please store them to the no corrosiveness and the well-ventilated room, the sterilized focusing laryngoscope should be kept according to the requirement for the asepsis.

From the date of the factory, product does not work within 12 months because of quality issues, we will repair for free, replace parts or products, life-long maintenance.

The following situations is not in the scope of warranty, we will provide paid service:

- 1) Human factors, e. g. using improperly, bump, choosing wrong disinfection method and maintenance;
- 2) Broken lens;
- 3) Demolition by self;

All kinds of the products can be updated or improved. If the configuration change, forgive us inform further.

9. Marking and signal

- 1) Tian Song®----- Company registered brand
- 2) “ A0013 ” and so on-----Product series number
- 3) Series code: The first two number is the year, next two is the month, then the work number, the last two is the quantity of this lot number. For example:05071120, it means the production date is July,2005, work number is 11, and the quantity of this lot number is 20

REF 72021 / D0104.1



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M-72021-GB-Rev.3.02.20