
Tian Song[®]

Model NP Urethro-cytoscopy set

Operating manual

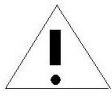
ZHEJIANG TIANSONG MEDICAL INSTRUMENT CO., LTD.

Content

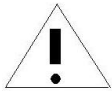
Symbol Description-----	1
Perface-----	1
1.Product usage -----	2
2.Main structure -----	2
3.Main feature, specification and the configuration-----	2
3.1 Main feature-----	2
3.2 Products configurationand diagram form -----	3
4.Applying field-----	5
5. Using Method-----	5
5.1 preoperative preparations-----	5
5.2 operating steps-----	6
6. Attention-----	7
6.1 Warning and attention -----	7
6.2 Cleaning, disinfection and sterilization -----	8
6.2.1 Cleaning -----	8
6.2.2 Disinfection and sterilization for endoscope-----	9
7.Contraindication （only for reference）-----	12
8.Maintenance and repair-----	12
9.Warranty-----	13
10.Marking and signal-----	14

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.

Perface

1. Please read the operating manual carefully before using our company Urethro-cystoscopy set, It may cause serious consequences if not following the instruction and warning in the manual.

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

3. Endoscope can be used with video and cold light source, to observe the status of body cavity.

Correct usage method: Firstly, be sure that the endoscopes is cleaning disinfected or sterilized before using (check the details in the part of cleaning, disinfection and sterilization); Inspecting endoscope, checking if there is damaged and normal working function; Connecting endoscope and light cable, connecting the other side of light cable to light source, Then according to relevant operating standard, the inserting point of endoscope refer to appropriate medical literature.

1、 Product usage

Model NP urethra-cystoscopy set is used for urologic urethroSurgery and bladder disease diagnosis and treatment.

2、 Main structure and specification

The model of Urethro-cystoscopy set is Model NP.

The urethro-cystoscopy set is composed of endoscope, sheath and the manipulator and endoscope bridge.

3、 Main feature and configuration

3.1 Main feature and parameter

Sheet 1 Endoscope identification and parameter

Serial no.	Content
1	Manufacturer:Zhejiang Tiansong Medical Instrument Co., Ltd. Add: No.168 Jianduan Road, Tonglu E&T Development zone, Hangzhou,China 311501
2	Name: urethro-cystoscopy set ID Number: NP
3	Maximum width of inserted part: 2.7mm、2.9mm 、4mm Working length: 205mm、302mm
4	Minimum width of instrument working channe:/
5	Visual direction θ : 0°、30°、70°
6	Field angle $2W$:65°
7	Designed optical working distance d_0 :20 mm
8	Resolution of field center, $^{\circ}r_{\alpha}(d)$:3.0C/(°)
9	Valid depth scope of optical frames: 3~100mm
10	Adopting A standards illumination spectrum in ISO 10526:1999 CIE S 005,the colour rendering index after illumination system and imaging system Ra: 89.7 Adopting D65 standards illumination spectrum in ISO 10526:1999 CIE S 005,the colour rendering index after illumination system and imaging system Ra: 88.9 The meaning of CRI:Characterize the stand of fall of endoscope aberration resolving power and colour reducibility.Ra is higher , which means the resolving power and colour reducibility is better . Transmission efficiency of optical energy—effective luminosity D_M : 1850cd/m ² /lm
11	Evaluating field shape characterization at the designed optical working distance

	 =20mm endoscope working field shape Illumination lens body effect of  90% field at the field form IL_{eR} : 0.60 Synthetical lens body effect of  90% field at the field form SL_{eR} : 0.35 Synthetical edge effect of  90% field at the field form SL_{e-ZE} : 0.17 Unit relative distorted control unit at the field form V_{U-z} : -18% Synthetical lens body lighting effect: The contribution combination of optical lens and imaging system to edge light effect.
12	There is no changeable parts by user
13	Professional after service , Add: No.168 Jianduan Road, Tonglu E&T Development zone, Hangzhou, China 311501
14	There is no obvious repid wear and broken parts of the endoscope
15	It is not allowed to curve the inserted part of endoscope.
16	The endoscope is without inserted part with special purpose which may cause safety harmful.
17	The endoscope liquid prevent classify is IPX7
18	According to electric shock prevent level, endoscope and light cable connected turned into BF type applied part

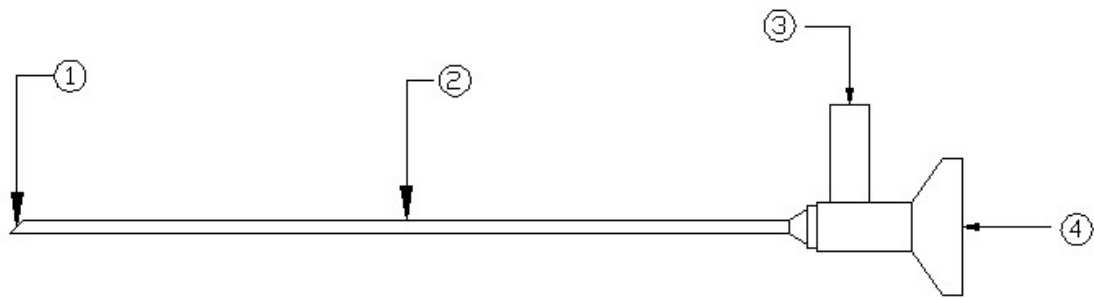
The product meets the demand of GB 9706.1、GB 9706.19

3.2 Products configuration and diagram form

Sheet2 Products configuration and

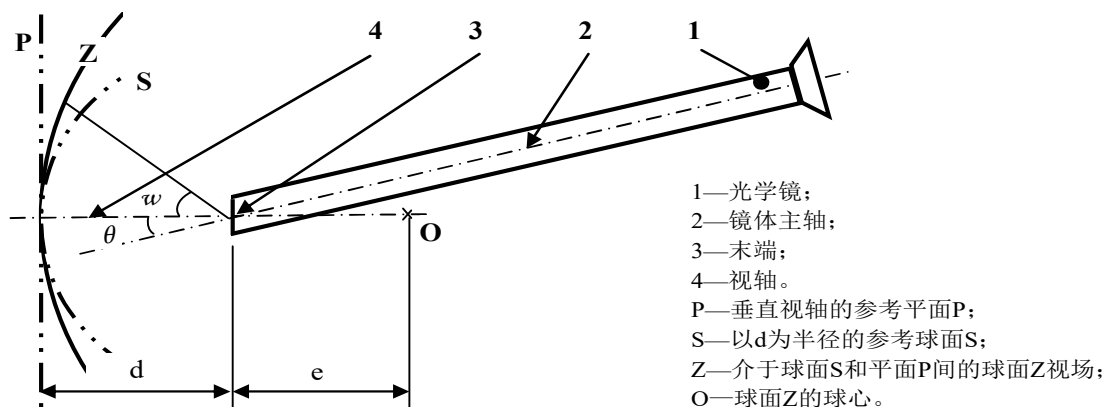
Item	Name	Code number	Quantity
Urethro-cystoscopy set	endoscope	A0010	1PC
	endoscope	A0210	1PC
	endoscope	A0310	1PC
	endoscope	A0012	1PC
	endoscope	A0211	1PC
	endoscope	A0022	1PC
	endoscope	A0312	1PC
	endoscope	A0013	1PC
	endoscope	A0313	1PC
	sheath	A1117 A1102.1	1PC
	manipulator	A1118 A1105.1	1PC
	endoscope bridge	A1119 A1106.1	1PC

1) Diagram form

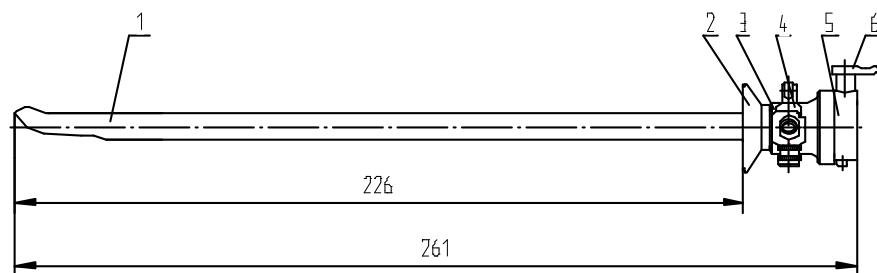


1、Objective lens 2、Mirror spindle 3、Optical cable interface 4、eyepiece

2) Working field model of endoscope

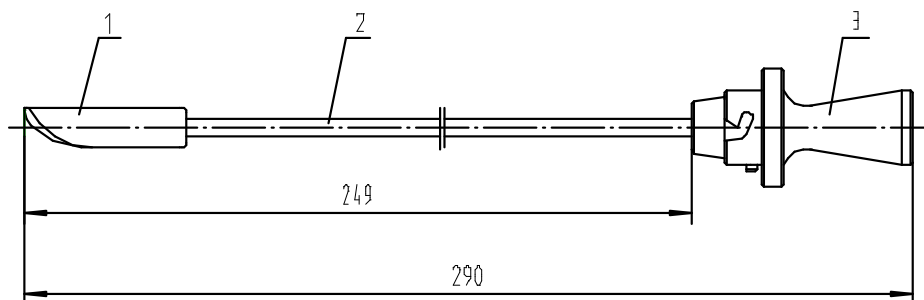


3) Sheath diagram



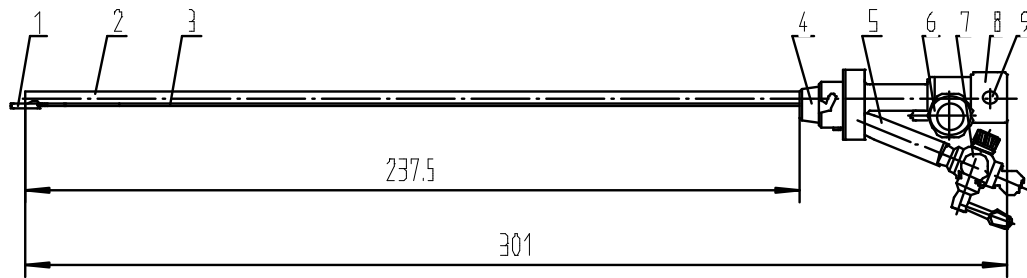
1.sheath 2.checking ring 3.Sheath body 4.valve 5.Front rand 6.Front button

Figure 2 outer Sheath diagram unit: mm



1.Plug 2.plug stick 3.handle
Figure3 obturator diagram unit: mm

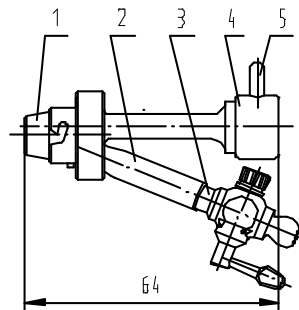
4) Manipulator diagram



1.plug 2.Operating tube 3.catheter 4.Operating body 5.Valve joint 6.handwheel 7.valve 8.Lock ring
9.Lock ring handle

Figure4 Manipulator diagram unit: mm

5) Endoscope bridge diagram



1.Bridge main body 2.Valve joint 3.Valve 4.Lock ring 5.Lock ring handle

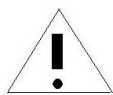
Figure5 Endoscope bridge diagram unit: mm

4、Applying field

Model NP Urethro-cystoscopy set is used for urologic Surgery diagnosis and treatment.

5、Using Method

5.1Preoperative preparation(only for reference)



Attention: During the use of Urethro-cystoscopy set, it may occur endoscope's failure (such as unclsinus imaging of lens body) or a subsidiary of equipment failure (such as the cold light bulb lighting failure), resulting in the loss of equipment's function. Therefore we suggest preparing spare equipment and parts before the operation to prevent any eventuality.

1) Definitude the diagnosis order, the inspector should ask the disease history carefully, and exam the body fully and together with the necessary testing, sometime

should add the necessities inspection.

2) Do hardly the instrument preparation according to the different examination to prepare the different type and the different specification endoscope and the endoscope parts. If have the condition, prepare one another set for spare. If check the all equipment are good or not, the disinfected instrument should be done the aquae sterilisata flushing. The lubricant only can use the glycerin and the glycerin preparation, should not be used by paraffin oil.

5.2 operating steps(only for reference)

1)Insert the sheath: This is the most important step for the successfully urethro-cystoscopy. Connect the obturator and the sheath, check the all input part all smoothly, lay on the lubricant(only glycerin or the glycerin preparation). Open the sheath two terminal valve switch, all the action should be lightly.

2)When the sheath and the obturator inserting to the bladder, you should take out the obturator, gather the urine by the glass to check the residue, and check the color is thickness or not. If the urine thickness, firstly you can flush the bladder by the asepsis water, when it clear then observe and flushing at same time, prevent inject more air.

3)Connect the sheath with the manipulator or the Endoscope Bridge, then insert the endoscope, and the sheath input valve connect to the pump by the water pipe. Next to connect the endoscope to the light source cable and the source then open the source, check all the connecting parts fixed or not, should not be loose to prevent the dropping harm to the instrument.

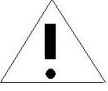
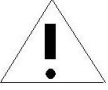
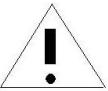
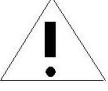
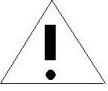
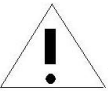
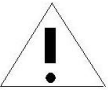
4)When checking the urethra, choose the 0 degree endoscope to observe the all sight of the urethra cavity. Check the bladder to observe sequence to confirm fully parts, by the sheath vacillation, rotating and the angle changing to observe the urethra and bladder all the parts.

5)When necessary, can choose the manipulator and through the relative instrument and choose the flexible forceps to do the biopsy check.

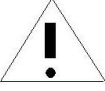
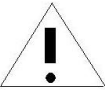
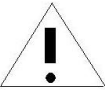
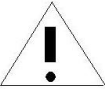
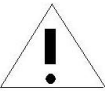
6)After the inspection, empty the bladder liquid, then pull out the sheath lightly.

6、Attention

6.1 Warning and Attention

- 1)  Attention: The endoscope can be used with the camera and light source which is conform to GB9706.19
- 2)  Warning: No matter orthophoria or Video connecting, always adjust light source to minimum and necessary light strength. The strength is higher, the endoscope end heat energy will be higher .
- 3)  Attention: Before using the Urethro-cystoscopy set surgery instrument, please read the manual and accessories manual carefully.
- 4)  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.
- 5)  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!
- 6)  Note: Wrong repeat using will make the instrument heavily damage and may cause the endanger.
- 7)  Attention: Please check the inserted part of Urethro-cystoscopy set if there is some roughened surface, acuity edge or the prominence on the instrument.
- 8)  Warning: Whenever discovering the anomaly of Urethro-cystoscopy set, he should immediately stop using it and extract slowly. It would be

harmful to patients if operating with faulted Urethro-cystoscopy set.

- 9)  Alarm: the Urethro-cystoscopy set endoscope head temperature will be up to 41℃, And the surface longtime 41 degree temperature will burn the adhibit. So, operator should choose the minimum illumining and the shortest time and the most properly distance to observe, and also avoid the fixing point observation, also do not make the endoscope near the adnibit so long.
- 10)  Note: the urethro-cystoscopy set is the now power product, but the product should be used together with the medical electrical products (Medical endoscope cold light source, camera, etc. The product meets the GB9706.1 and GB9706.19 connection requirement.
- 11)  Alarms: All the time can not see the cold light source directly by eye, otherwise will harm to the eye.
- 12)  Attention:Inspection explanation can be got at the operating instruction condition: ①Check the products through visual method, to be sure products no corroding,no impression ,no scratch. ②Check image quality:the words can be seen clearly through optical visual tube at the distance 30mm to objective end.
- 13)  Note: the other equipment connected to the urethro-cystoscopy set should be in conformity with the standard requirements of medical electrical equipment.

6.2 Cleaning, disinfection and sterilization

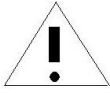
6.2.1Cleaning

- ①Rinsing thoroughly with flowing water immediately after using , removing residual matter such as blood,grume and wipe dry.
- ②Soak the endoscopes into multienzyme lotion after drying.
- ③Rinsing thoroughly endoscope pars,lumen should be washed by water torch,the parts which is detachable should be seperated,and washed by ultrasonic cleaner for 5min-10min.
- ④Tube intracavity should be washed by brush, but pay attention to avoid surface

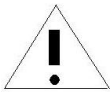
scratch.

⑤ Special cleaning tool or equipment explanation

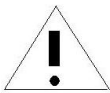
The endoscope can be cleaned by the cleaning machine which is only for endoscope, refer to the machine manual



Attention: If there is still residual matter on light cable surface, it will effect the light leading property, therefore, the residual matter must be cleaned.



Warning: High powered light will be overflowed from the light cable. The temperature can reach 41℃ at endoscope end center 8mm distance. Therefore, please do not let the body tissue or combustible material direct contact endoscope end. If you are working at a near distance, please turn down the light strength.



Attention: To prevent fogging during operation, be sure eyepiece and optical imaging system interface dry.

In order to assure the parts (handle and endoscope) connecting together firm and safe, The connecting sealing place of endoscope and handle can't be dirty or damaged.

6.2.2 Disinfection and sterilization

① Disinfection explanation

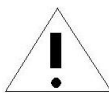
1) Endoscope can be disinfected in 2% glutaraldehyde advanced solution which is specialized for endoscope.



Warning: The solution which concentration of glutaraldehyde higher than 2% can't be used, which will damage endoscope.

2) Place endoscope in individual plastic container, plasticainer can avoid endoscope scratch and electrolytic etching between different metal in same solution. Do not soak endoscope and instruments together to avoid damage to endoscope

3) Add activator into glutaraldehyde to be glutaraldehyde solution, shake up, inspect the PH between 8.2 and 8.9, to be sure the activatory glutaraldehyde solution with best antibacterial activity. Mark excitation and losing date on vessel.



Attention: Looking for related detail information of glutaraldehyde solution and the instruction refer to glutaraldehyde manufacturer.

4) Adopt velveteen less and sterility cloth to dry endoscope.

② Sterilization explanation

1) ETHYLENE OXIDE STERILIZATION

- a. Put endoscope in sterility tray.
- b. All the sterilization circulation must include one pretreatment circulation.
- c. The EO sterilization data in Sheet 3 is verified and effect.

Sheet 3 EO Sterilization valid parameter

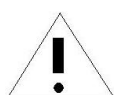
Gaseous mixture	Ethylene oxide .tetrafluoroethane
Temperature	54.4℃±2.8℃ (130°F±5°F)
Relative humidity	60%±20%
Pressure	55.1Kpa～68.9Kpa (8psi～10psi)
Processing time	120min
Concentration of EO	600mg/L±30mg/L

Gaseous mixture is composed by 10% Ethylene oxide and 90% tetrafluoroethane

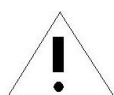
d. Endoscope can be finished at any fumig cupboard, keep temperature 48.9℃～54.4℃ (120°F±130°F), 12h

2) Steam sterilization

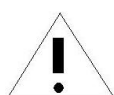
Endoscopy labeled "AUTOCLAVE" means it can use high temperature and high pressure steam sterilization.



Attention: Temperature sudden changes may be caused endoscope mirror glass parts rupture. Do not immediately exposed endoscope to air when it remove from autoclave environment.



Attention: Can not be used the cold, sterile liquid cooling endoscope. Forced cooling may cause serious damage to the endoscope.



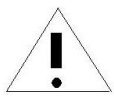
Attention: Before using the high pressure steam sterilization, all endoscopy must be thoroughly cleaned and must completely remove all organic material, blood, and the cleaning solution.

- a. Put the endoscope on the sterilizing tray.
- b. Pre vacuum or high vacuum sterilization includes four basic stages: preparation

stage, treatment stage, exhaust stage, drying stage. Through the vacuum to remove the air, put the equipment into. when the temperature reached 134℃, the pressure value of 2par, entering the second stage, it cost 4min. The exhaust stage means elimination of all the steam in the room. Finally pumping vacuum once again, let equipment in vacuum drying about 20 min.

- c. Put the tray on the sterilizer must ensure steam enough circulation, eliminate air movement and condensed water. Put sterilizer loose make the best effect in sterilizing agent.
- d. After steam sterilization cycle, Do not touch endoscopy before enough cooling .

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 Arthroscopy set, patient and the Arthroscopy set should do the strictly sterilization, and the sterilizing vessel also should be separately strictly from the other patient. If using the special Arthroscopy set is difficult, also should do the sterilizing or high level disinfecting.

2) The Arthroscopy set sterilized by the chemosterilant, firstly should be cleaned by aseptic water to clean the rest disinfectant.

● **Sterilization and disinfection of other parts**

1) The surgical instruments used with Arthroscopy set should be sterilized after cleaning.

2) Steam sterilization, its use conditions and methods refer to the endoscope sterilization.

3) Ethylene oxide sterilization can also be used, the methods and notes refer to the sterilization of Arthroscopy set.

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

5) 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.

6) Other unaccomplished matter and specific method check <Endoscope

cleaning,disinfection regulation for technical opeartion(2004 version)> and < Hospital disinfection technical regulation>

7)The listed cleaning ,disinfection and sterilization equipment in this chapter and the operation method ,step and technical parameter for chemical agent is only for reference. The detail operation method and step and parameter should refer to equipment and agent instruction.

7、Contraindication (Only for reference)

Strictly grasp the contraindication not only can reduce the unnecessary the pain, more important is to avoid the prevent the complication occurring.

1) Narrow urethra: especially to check the no consider the narrow may be met the resistance and still force to insert, may make the urethra trauma or perforation.

2) If the bladder capacity is less then 50ml; if not understand the capacity, then the operation will perforation continuously. If the bladder capacity is too small then despite the procedure are not trauma, the observation are still not satisfied.

3) Actue urinary tract infected person;

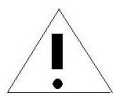
4) Whole hemorrhagic disease person should avoid this diagnosis

5) Acute systemic severe infection

6) Menstruation and pregnancy women

7) Patients with isolated kidney, uremia and giant renal pelvis should be operated carefully.

8、Maintenance and Repair



Note: The products are can not 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 urethro-cystoscopy set.

The urethro-cystoscopy set 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 rulely, can not disinfected by random. Disinfecting strictly follow the regulation avoid damagement.

2) If the urethro-cystoscopy 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) All different instruments must be clean after using , every joint should be open,clean inside with swab or speical detergent,The formainule or groove of the instruments should be clean by long and small brush or swab.The opening and closing parts should be cleaned by soft brush. Inspection carefully after instruments cleaning, then dry and hang over in the container standby.

4) The endosocpe is rigid ,it is not allowed to curve the insert parts, otherwise the endoscope will be damaged.

5) The explanation about EMC

This system is conform to the requirement of EMC in IEC60601-1-2. During using,followed EMC requirement must be attention and adopting suitable precautionary measure.The accessories which is accepted by our company can be used with the endoscope. Portable or movable type high frequency communication equipment can't be used near the system, because they may cause system function damage.The system meets the limit of A class authentication radiation frequency. But ,it may not eliminate the distraction caused by the nearby high frequency equipment.(such as TV or radio).If there is such distraction ,please contact our company.

8) Transportation term: Environment temperature: 5℃ ~ 40℃

Relative humidity: ≤80%

Storing condition: Environment temperature: -20℃ ~ +60℃

Relative humidity: 10%~ 80%

Air pressure: 500KPa~1060KPa

9) The urethro-cystoscopy is the electric product, can not be discarded together with the household garbage.When the service life is finished ,please dispose according to laws and regulations requirement .

9、Warranty

①From 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.

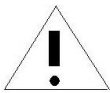
②If there is human factor problem in guarantee , our company will provide paid service.

③ If the products with problem after guarantee period , our company will provide paid service.

④ Please pack and delivery repaired products according to our company requirement.

⑤ Please check the quality when receiving the repaired products, if there is still quality problem, please contact with service department immediately. If there is no feedback within three days (the date when the package is arriving), it will regard as the quality confirmed.

Please contact our service depart for detail information



Attention: please be sure the products is disinfected before delivery.

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.

10、Marking and signal

- 1) Tian Song®-----Company registered brand
- 2) “A0012”and so on ----- Product code number
- 3) NP-----Product model
- 4) Instruments series code: The first two number is the year, next two is the month, then the series number and work number, For example:100521426, it means the production date is May,2010, Series number is214, and worker number is 26.
- 5) Endoscope series code: The first two number is the year, next two is the month, then the series number and work number, For example:10031010102, it means the production date is March,2010, series number is 101, worker number is 01 and the quantity number is 02.

Manufacturer:ZHEJIANG TIANSONG MEDICAL INSTRUMENT CO.,LTD.

Producing add:No.168 jianduan Road, Tonglu E&T Development zone, Hangzhou,China.

Registration Add: No.168 jianduan Road, Tonglu E&T Development zone, Hangzhou,China.

Service: ZHEJIANG TIANSONG MEDICAL INSTRUMENT CO.,LTD.

Service Add: No.168 jianduan Road, Tonglu E&T Development zone, Hangzhou,China.

After service Tel: 0571-64241668 64241158

Fax: 0571-64241918

Code:311501