

## INSTRUCTION FOR USE

# Spinal Endoscope

## 椎间盘镜



Dragon Crown Medical Co., LTD

Registered Address: No.109 Shunhua Road, High-Tech Development Zone, Jinan, Shandong, 250101, China.

Production Address: B1, F1, F4, F5, F6, F7, F8 and East House, Engineering & Technology Center Bldg., No.978 Tianchen Road, High-Tech Development Zone, Jinan, Shandong, 250101, China.

Tel: +86-531-81217461;

Fax: +86-831-81217299

Website: [www.dcvertebrae.com](http://www.dcvertebrae.com)

Revision: SGL/CE-07-H A/1

Date: Jul.,9,2024

## 1. Product name 产品名称

Spinal Endoscope

椎间盘镜

## 2. Specifications and models 规格型号

DCZJ- II, DCZJ- III。

## 3. Product Performance 产品性能

Spinal Endoscope is a rigid tube endoscopic instrument designed by the company for minimally invasive surgery according to clinical needs. Its characteristic is that under the premise of less trauma, through the medical camera, the surgical field of view is transmitted to the monitor, with high conductivity optical fiber, so that the surgical field has enough illumination, the doctors complete the operation by observing the image on the monitor screen, and use special instruments. Because the endoscope will enlarge the surgical field of view, making the operation safer.

椎间盘镜是公司根据临床需要设计用于微创手术的硬管内窥镜器械。其特点是在较小的创伤前提下，通过医用摄像机，将手术视野传输到监视器上，配以高传导性能的光纤，使手术视野有足够的照明，医生通过观察监视器屏幕上的图像，使用专用的器械进行操作，完成手术，由于内窥镜将手术的视野进行了放大，使手术更加安全。

This product belongs to the application part (whole) of BF type equipment, waterproof class is IPX7, no physiological effect risk. It is clinically used with medical cameras and cold light sources that meet the national Class I BF safety requirements.

本产品属于BF型设备的应用部分(整体)，防水等级为IPX7，无生理效应危险。在临床上与符合国家I类BF型安全要求的医用摄像机和冷光源配合使用。

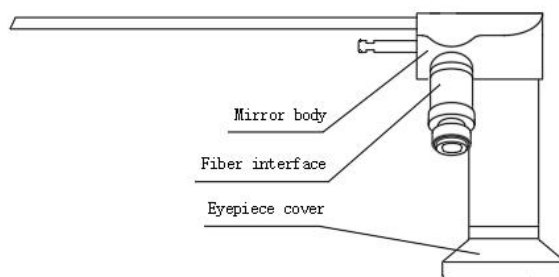
The Spinal Endoscope should be used by a trained doctor, and the operator should read the IFU carefully before use and be familiar with the use of the Spinal Endoscope. This product can be reused.

椎间盘镜应由经过相关培训的医生使用，操作者使用前须详细阅读使用说明书，并熟悉椎间盘镜的使用方法。本产品可重复使用。

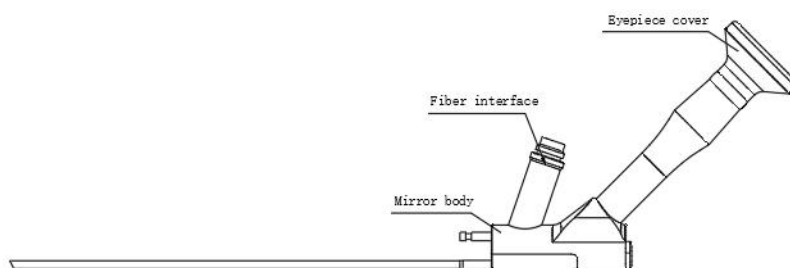
## 4. The main structure of the product 产品主要结构组成

The Spinal Endoscope consists of an eyepiece cover, a mirror body and an optical fiber interface. The schematic diagram of product structure is as follows:

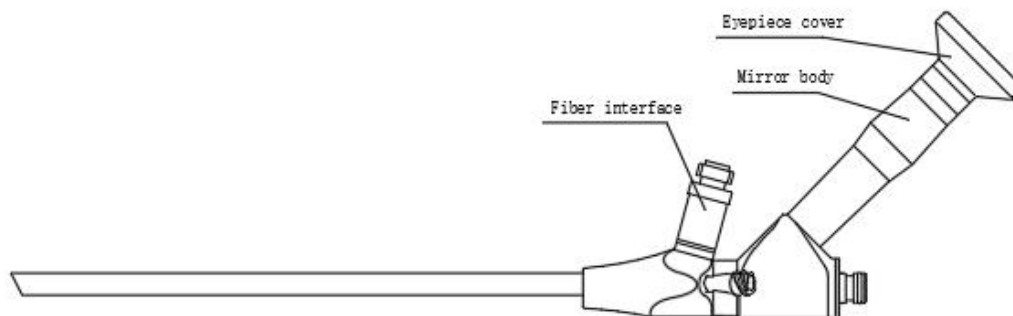
椎间盘镜由目镜罩、镜体和光纤接口组成。产品结构组成示意图如下：



DCZJ- II: 3.0×105



DCZJ- III: 2.7×150/2.7×180



DCZJ- III: 6.3×125/6.3×181/ 6.9×181/10.0×125

## 5. Indications 适应症

All types of intervertebral disc herniation and prolapse; Spinal stenosis; Intervertebral foramen stenosis; Intervertebral space infection; Discogenic low back pain and so on.

所有类型的椎间盘突出、脱出症；椎管狭窄；椎间孔狭窄；椎间隙感染；椎间盘源性腰痛等。

## 6. Contraindication 禁忌症

- Mental patients. 精神病患者
- Pregnant women and others unfit for surgery. 孕妇和其他不适合手术者

## 7. Patient target group 患者目标群体

Those who need to use this product for surgery are evaluated by doctors.

由医生评估需要使用本产品进行手术者。

## 8. Warning 警告

- (1) Type III Spinal Endoscope 6.3\*181/6.3\*125/6.9 has a circular instrument channel with diametric 3.7mm, 3.75mm and 4.1mm respectively. Users should pay attention to the selection of suitable instruments.
- (2) The liquid used in clinical operation, cleaning and sterilization of this product includes: normal saline, routine injection liquid, purified water for cleaning, alcohol, multi-enzyme lotion or cleaning solution for endoscope; Do not use disinfectants containing peracetic acid, phenol, chlorine-containing components without anti-corrosion protection, and various adhesives or liquids that may cause corrosion to stainless steel.
- (3) Due to the high temperature of the tube outlet, do not place the endoscope on heat-sensitive materials (such as covering cloth, etc.) to avoid burning or even burning.
- (4) When used in combination with a high-performance light source, the temperature of the light emitting part of the Endoscope may exceed 41°C, causing burns at the surgical site. Therefore, direct contact between the Spinal Endoscope and the tissue should be avoided. If possible, increase the flushing of the operating area and promptly suction out the generated steam with a negative pressure suction tube.
- (5) Damage to the endoscope will cause blurred images, and continued operation may cause harm to the patient, so the operation should be stopped and changed to open surgery or other measures.
- (6) There is potential electromagnetic interference between the device and other devices. Please try to stay away from other electronic devices when using.
- (7) Optical accessories fade due to X-ray radiation, which can cause damage to the endoscope. Using CT or X-ray and endoscope at the same time can lead to danger. Because the magnetic field can cause movement/migration or heat, some metals of the endoscope can be dangerous in the examination, so such patients should not use MRI scans. The optical and electrical medical instruments of endoscopes can be damaged by magnetic forces. The metal of the endoscope can cause side effects and visual interference. Using MRI and endoscope at the same time can be dangerous.
- (8) Modification of the device is not permitted.

- (9) At no time should you look directly at light from cold light sources, optical cables or endoscopes with your eyes, which can damage your eyes.
  - (10) The F-type application part is provided by the insulation between the supply device and the optical beam delivery outlet.
  - (11) Before each use, or after changing the viewing mode/setting, check to ensure that the image viewed through the endoscope is live (and not a stored image).
  - (12) This device does not have automatic cleaning function.
  - (13) Do not stretch the nerve or contact the meninges during the use of this product.
1. III型椎间盘镜 6.3\*181/6.3\*125/6.9 带有圆形器械通道, 直径分别是3.7mm, 3.75mm 和 4.1mm, 用户应注意选择适用的器械。
  2. 本产品临床手术和清洗灭菌使用的液体包括: 生理盐水、常规注射液体、清洗用的纯化水、酒精、多酶洗液或内窥镜专用的清洗液; 不能使用 含无防腐保护的过乙酸、苯酚、含氯组分的消毒剂以及各类粘合剂或可能对不锈钢产生腐蚀的液体等。
  3. 由于镜管出口的温度很高, 不要将内窥镜放在热敏感的材料(如覆盖布等)上面, 避免烧坏甚至燃烧。
  4. 与高性能光源结合使用时, 窥镜光射出部分的温度可能会超过 41°C, 造成手术部位灼伤, 因此要避免椎间盘镜与组织的直接接触, 如果可能, 可以适当增加操作区域的冲洗, 并及时将产生的 蒸汽用负压吸引管吸出。
  5. 内窥镜损坏将造成图像模糊, 继续操作可能会对病人造成伤害, 应停止操作, 改为开放手术或其他措施。
  6. 该设备与其它装置之间存在潜在的电磁干扰, 使用时请尽量远离其它电子设备。
  7. 由于 X 线辐射, 光学配件会褪色, 因此会导致内窥镜受损。同时使用 CT 或 X 线和内窥镜会导致危险。由于磁场会引起移动 / 迁移或发热, 内窥镜的某些金属在检查中会有危险性, 所以这样的病人禁止使用 MRI 扫描。内窥镜的光学和电力医疗器械有可能被磁力损伤。内窥镜的金属会导致副作用和可视的干扰。同时使用 MRI 和内窥镜会导致危险。
  8. 不准许改装本设备。
  - 9.任何时候都不要直接用眼睛去看冷光源, 光缆或内窥镜发出的光, 这会损害眼睛。
  - 10.采用供给装置与光束束出口间的绝缘, 提供了F型应用部分。
  - 11.每次使用前, 或改变观察模式/设置后, 应检查以确保通过内窥镜观察到的图像是实时(而不是存储的图像)的。
  12. 本设备不具有自动清洁功能。
  - 13..本产品使用过程中不可牵拉神经, 不能接触脑膜。

## 9. Safety tips 安全提示

- (1) In order to protect the endoscope from loss of function, prepare a spare endoscope before each use.
- (2) Before each use, it is necessary to check the part of the Spinal Endoscope and endoscope accessories inserted into the human body, and there must be no rough surface, sharp edges and sharp edges or protrusions, incomplete or loose parts that may cause safety hazards.
- (3) Before each use, the Spinal Endoscope and related Spinal Endoscope auxiliary equipment must be checked for optical or mechanical damage. Do not use damaged Spinal Endoscopes.
- (4) When the high-frequency instrument is used, the current conducting part should be in the field of view and in contact with the specified position, and the high-frequency current conducting part can be powered on only when the distance between the high-frequency current conducting part and the end of the endoscope or the working sleeve is more than 10mm. Please refer to the use instructions of the high-frequency instrument manufacturer.
- (5) When using high-frequency devices, it should be noted that the leakage current of the patient may be accumulated. The maximum rated repeat peak voltage of the device used by the user is 1000V, and a higher repeat peak voltage should not be used.
- (6) High-frequency isolation and/or insulation are provided by the high-frequency accessories and/or equipment used for interconnection.

- (7) When a type III Spinal Endoscope is used, an instrument that can pass through the instrument channel on the Spinal Endoscope must be used, where the surgical forceps should be introduced or removed visually from the instrument channel of the mirror when the mouth of the forceps is closed. If larger tissue is clamped, it can be removed from the working cannula along with the endoscope.
- (8) Do not use high frequency devices in the presence of flammable anesthetics, excessive gas injection, high concentration explosive gases, inert gases or laser assisted gases to avoid gas embolism.
- (9) When the endoscope device is used with accessories, other ME devices and/or non-ME devices within the scope of the endoscope application configuration, there should be no similar design resulting in incorrect links to avoid the risk of simultaneous use.
1. 为了对内窥镜设备功能失去危害进行防护，每次使用前，请准备一支备用内窥镜。
2. 每次使用前，必须检查椎间盘镜和内窥镜附件插入人体内部的部分，不能有可能引起安全性危害的粗糙表面、锋利的棱角和尖锐边缘或突出物，不完整或松动的部件。
3. 每次使用前，必须对椎间盘镜及相关的椎间盘镜辅助设备进行检查，看其是否有光学或机械损坏，不要使用有损坏的椎间盘镜。
4. 使用高频器械操作时，电流传导部件应在视野之内并接触到指定部位时，且高频电流传导部件与内窥镜末端或工作套管有 10mm 以上的距离时才能高频器械通电，请参阅高频器械制造厂商的使用说明。
5. 使用高频器械时应注意，可能会累积增加患者漏电流，使用者所使用器械的最大额定重复峰值电压为 1000V, 不得使用更高的重复峰值电压。
6. 高频隔离和(或)绝缘由所互连使用的高频附件和(或)设备提供。
7. III型椎间盘镜使用时，必须使用能够通过椎间盘镜上的器械通道的器械，其中手术钳应在钳口闭合时，在目视下才可以从镜子的器械通道内导入或导出手术钳。如夹持较大组织时，可以连同内窥镜一起从工作套管中取出。
8. 不要在易燃麻醉剂、过量气体喷注、高浓度爆炸性气体、惰性气体或激光辅助气体存在时使用高频器械，避免导致气体栓塞。
9. 当内窥镜设备在内窥镜应用配置范围内，和附件、其他 ME 设备和/或非 ME 设备一起使用时，不能有相似的设计而产生错误链接，避免因为同时使用而造成风险。

## **10. Usage method 使用方法**

### **(1) Operating conditions 运行条件:**

Temperature range: 5°C ~ 40°C; Relative humidity range: ≤80%; Atmospheric pressure range: 70kPa ~ 106kPa. Free of corrosive gases and well-ventilated interior.

温度范围：5°C~40°C；相对湿度范围：≤80%；大气压力范围：70kPa~106kPa。无腐蚀性气体和通风良好的室内。

### **(2) Check 检查**

The Spinal Endoscope must be checked before each use:

每次使用前必须对椎间盘镜进行检查：

Check the product: make sure it is free from rust, indentation, scratch, bending, deformation and broken lens.

检查产品：要确保它无锈蚀、无压痕、无划痕、无弯折、无变形、无镜头破损。

Check the image quality: the text about 30mm from the end of the objective lens should be clearly seen through the optical tube.

检查图像质量：通过光学视管应该能清晰地看到距离物镜端约30mm 的文字。

### **(3) Clinical Use 临床使用**

- a. According to surgical requirements, the posterior (interlaminar) approach of the spine was generally selected for DCZJ-II 3.0×105, DCZJ-III 2.7×150, 6.3×125, and 10.0×125, and DCZJ-III 2.7×150, 2.7×180, 6.3×181. 6.9×181 spinal lateral posterior approach was selected, DCZJ-III 2.7×150 anterior cervical approach was selected, and after X-ray positioning,

percutaneous puncture was performed to expand step by step, and finally the working cannula was placed to complete the establishment of the working channel.

根据手术需要，一般 DCZJ- II型 3.0×105、DCZJ- III型 2.7×150,6.3×125和 10.0×125 选择脊柱的正后方(椎板间)入路，DCZJ- III型2.7×150，2.7×180，6.3×181，6.9×181 选择脊柱的侧后方入路，DCZJ- III 型 2.7×150 选择颈椎的前方入路，经 X 光定位后，经皮穿刺逐级扩张，到最后置入工作套管，完成工作通道的建立。

- b. DCZJ- II 3.0×105 and DCZJ-III 2.7×150,2.7×180 intervertebral disc lenses should be stuck on the entry frame first and then fitted on the working sleeve, and the position and height should be determined before fixing the frame; Type III Spinal Endoscopes 6.3× 125,6.3 × 181,6.9 × 181 and 10.0×125 can be directly inserted into the working tube, and the normal saline is connected to the flushing valve on the scope to adjust the appropriate water flow.

DCZJ- II型3.0×105 和 DCZJ- III型 2.7×150,2.7×180椎间盘镜要先卡入境架后再套在工作套管上，确立位置和高度后固定镜架；III型椎间盘镜 6.3×125，6.3×181，6.9×181和10.0×125 可直接和置入工作套管内，将生理盐水与窥镜上的冲洗阀连接，调节合适的水流量。

- c. Connect the endoscope to the camera lens port and the optical fiber, and fasten it firmly.

将内窥镜与摄像镜头接口和光纤连接，卡牢、拧紧。

- d. Turn on the camera, cold light source, and monitor switch (If you need to adjust the white balance, point the white paper or gauze without reflective, press the white balance button for 5 seconds), rotate the focus ring on the camera, adjust the focus length until the image is clear, and rotate the camera to adjust the direction of the image.

打开摄像机、冷光源、监视器开关(如需调整白平衡，可对准无反光白纸或纱布，按白平衡按钮 5 秒钟)，旋转摄像头上的调焦环，调整焦距至图像清晰，整体转动摄像头可调整图像的方向。

- e. In use, if there is blood or other tissue in the lens, water can be flushed into the working tube or the Spinal Endoscope can be removed and wiped to ensure a clear image. When taking out, it should be slowly pulled out, do not exert too much force.

使用中，如镜头有血或其他组织，可向工作套管内注水冲洗或取出椎间盘镜擦拭，以保证图像清晰，取出时应慢慢向外拔出，切忌用力过猛。

## 11. Spinal Endoscope cleaning, sterilization and maintenance 椎间盘镜清洗、灭菌与保养

- (1) The Spinal Endoscope is provided in a non-sterile state, and must be cleaned and sterilized before use. The cleaning process does not require disassembly.

椎间盘镜为非灭菌状态提供，在使用之前务必进行清洗和灭菌工作。清洗过程无需拆卸。

- (2) Processing restrictions and constraints: the damaged disc scope can not continue to use; Spinal Endoscopes that have reached the limit of times of use should not be used any longer.

处理限制和约束：造成损坏的椎间盘镜不可继续使用；达到使用次数限制的椎间盘镜则不可继续使用。

- (3) Initial treatment: the pollutants on the surface of the Spinal Endoscope should be initially removed under running tap water within 30 minutes after use, and the water stains on the surface of the Spinal Endoscope should be wiped clean; If the disc scope cannot be handled immediately, it should be kept damp during transport, covered with a wet towel or placed in a tray with running water.

初始处理：使用后应在30分钟以内流动的自来水下初步去除椎间盘镜表面的污染物，并擦拭干净椎间盘镜表面水渍；如果椎间盘镜不能立即处理，在运输过程中应保持潮湿，可用湿毛巾盖住或者放置在装有自来水的托盘中。

- (4) Transport and container: should be equipped with Spinal Endoscope tray transported to the special work area for processing; Contaminated and uncontaminated Spinal Endoscope should be transported separately to avoid human and environmental contamination.

运输与容器：应将装有椎间盘镜的托盘运送到专用的工作区域处理；被污染的椎间盘镜和未被污染的椎间盘镜应分开运输，避免人员和环境污染。

- (5) Cleaning agent and cleaning tools: It is recommended to use a multi-enzyme cleaning agent with a concentration of 0.5%, special soft brush, soft cloth, and dust-free cloth. Multi-enzyme cleaners are used in accordance with the manufacturer's instructions for use.

清洗剂和清洗工具：建议使用浓度为0.5%多酶清洗剂，专用软毛刷、软布、无尘布。多酶清洗剂按照制造商规定的使用方法使用。

(6) Cleaning /清洗

- a. Clean the Spinal Endoscope with purified water for at least 3 minutes to remove residual substances such as blood and tissue. Use a soft cloth to remove any remaining dirt from the Spinal Endoscope scope. (processing temperature: 15 ~ 30°C).

用纯化水对椎间盘镜进行清洗，至少清洗3min，除去血液、组织等残留物质。使用软布擦掉整个椎间盘镜上的残留污垢。(处理温度：15~30°C)。

- b. Check the end of the Spinal Endoscope for damage, and make sure that the lens at the end is intact and firmly in the proper position, and check whether it has exceeded the number of uses.

检查椎间盘镜端头是否存在损坏，并确认端头处镜头完好并牢固地处于适当的位置，检查是否超过使用次数。

- c. Prepare 0.5% medical multi-enzyme low-foam detergent diluted with purified water in a suitable container, so that the whole Spinal Endoscope can be completely soaked for 20min (processing temperature: 25~30°C).

合适的容器中准备纯化水稀释后的 0.5%医用多酶低泡清洗剂，使其可以完全浸泡整个椎间盘镜，浸泡 20min(处理温度：25~30°C)。

- d. After soaking, wash the whole Spinal Endoscope with a soft brush and the lumen with a special soft brush for at least 2min to remove all visible contaminants (processing temperature: 25~30°C).

浸泡后用软刷刷洗整个椎间盘镜，管腔内用专用软刷刷洗，至少刷洗2min，去除所有可见污染物（处理温度：25~30°C）。

- e. All parts of the Spinal Endoscope should be thoroughly cleaned with purified water (at least 30s), and the lumen should be thoroughly washed with a high-pressure water gun (at least 20s) (processing temperature: 15 ~ 30°C).

用纯化水彻底清洗椎间盘镜各部位(至少 30s)，管腔应当用高压水枪彻底冲洗(至少 20s)(处理温度：15~30°C)。

- f. Wipe the end with a dust-free cloth until the dirt is completely removed.

使用无尘布擦拭端头直至污垢完全去除。

- g. Rinse the entire Spinal Endoscope with purified water for at least 60 seconds until visible dirt and cleaning agent are completely removed (processing temperature: 15 ~ 30°C)

用纯化水漂洗整个椎间盘镜至少 60 秒钟，直至可见污垢和清洗剂完全去除(处理温度：15~30°C)

- h. First drain all water, and then completely dry the Spinal Endoscope end and all surfaces with a soft and absorbent cloth. Use a pressure air gun to blow out any remaining water traces on the Spinal Endoscope surface and inside the channel cavity (do not use compressed air on the Spinal Endoscope end).

首先排空所有水分，然后用柔软和吸收性强的布将椎间盘镜端头和所有表面完全擦干，可先用压力气枪吹出椎间盘镜表面及通道腔体内的残留水迹(切勿在椎间盘镜端头使用压缩空气)。

- i. Place in a drying oven at 80 ° C (set temperature) for at least 30min and ensure that the Spinal Endoscope is dry before moving to the next step.

放入 80°C(设定温度)干燥箱内进行处理，时间至少 30min，在移至下一步骤之前确保椎间盘镜已经干燥。

- j. Check the entire Spinal Endoscope for dirt under a magnifying glass. If dirt is still present, repeat the entire cleaning process.

在放大镜下检查整个椎间盘镜是否存在污垢。如果污垢仍然存在，则重复整个清洗流程。

- (7) Inspection and maintenance: After cleaning, the Spinal Endoscope must be checked, and the inspection should be thorough.检查与维护：清洁后必须对椎间盘镜进行检查，检查应彻底。

Check the product: to ensure that it is free from rust, indentation, scratch, bending, deformation and broken lens.

Check the image quality: the text about 30mm from the end of the objective lens should be clearly seen through the optical tube.

检查产品：要确保它无锈蚀、无压痕、无划痕、无弯折、无变形、无镜头破损。

检查图像质量：通过光学视管应该能清晰地看到距离物镜端约 30mm 的文字。

#### (8) Sterilization 灭菌

- a. The sterilization of the Spinal Endoscope should be put into a special disinfection box, and then the sterilization box should be double-wrapped with a standard non-woven fabric or a moisture-proof surgical sterile bag. Or follow the rules of your local medical institution.
- b. Can use steam sterilizer (Shandong Xinhua Medical Equipment Co., LTD.; Model MOST-T; Volume 80L). The sterilization parameters were temperature 134°C, pressure 201.7kPa-229.3kPa, sterilization time 4min, and drying time 30 minutes. It is the responsibility of the user to ensure that the sterilization procedure has achieved the specified sterilization effect.

Note: The sterilizer in the manual is recommended. If the user changes the sterilizer, the sterilizer should be verified by himself.

1 椎间盘镜灭菌应放入专用消毒盒，然后再使用标准的无纺布或防潮手术灭菌包对消毒盒进行双层包裹。或者遵循当地医疗机构的相关规定。

2 可采用蒸汽灭菌器(山东新华医疗器械股份有限公司；型号MOST-T；容积80L)。灭菌参数为温度 134°C，压力 201.7kPa-229.3kPa，灭菌时间 4min，干燥时间30min。使用者有责任确保上述灭菌程序已达到规定的灭菌效果。

注：说明书中灭菌器为推荐使用，如使用者更换灭菌器，需自己对灭菌器进行验证；

- (9) Storage: sterilized products should be classified, stored in the sterile goods storage area in separate racks. The ambient temperature should be < 24°C, relative humidity should be less than 70%, medical non-woven packaging products are valid for no more than 180 days. Or follow the rules of your local medical institution.

贮存：灭菌后产品应分类、分架存放在无菌物品存放区，其环境温度应<24°C，相对湿度应低于70%，医用无纺布包装的产品有效期不超过180天。或者遵循当地医疗机构的相关规定。

## 12. Maintenance, storage and transportation 维护、贮存和运输

- 1) The Spinal Endoscope is a precise optical instrument, and must be used with care to avoid collision between other instruments and the mirror tube, especially the mirror tube is very sensitive to bending pressure, and too much force may cause damage to the optical components and make it impossible to use.
- 2) The surface of the Spinal Endoscope can not be wiped with hard objects, and high care should be taken when cleaning the Spinal Endoscope to avoid bending the mirror tube under pressure, and to prevent impact and fall, resulting in losses.
- 3) The Spinal Endoscope should be stored in the atmospheric pressure range of 70kPa ~ 106kPa, the temperature of -20°C~ 45°C, the relative humidity is not more than 80%, no corrosive gas and good ventilation room; Transport conditions are atmospheric pressure range 70kPa ~ 106kPa, temperature -20°C~ 45°C, relative humidity is not more than 80%.
- 4) In order to avoid damage to the endoscope in transit, we recommend using the original packaging during delivery and repair.
- 5) The disposal of equipment and packaging materials and accessories shall comply with the relevant national environmental protection regulations.

1. 椎间盘镜为精密的光学器械，使用时必须小心，避免其他器械对镜管碰撞，尤其是镜管对弯曲的压力很敏感，受力过大可能会导致光学元件的损坏而不能使用。

2. 椎间盘镜的表面不能用硬质的物体擦拭，在清洁椎间盘镜时要高度小心，避免受压力使镜管弯曲，谨防撞击、跌落，造成损失。



3. 椎间盘镜应贮存在大气压范围70kPa~106kPa, 温度 -20℃~45℃, 相对湿度不超过 80%, 无腐蚀性气体和通风良好的室内; 运输条件为大气压范围70kPa~106kPa, 温度 -20℃~45℃, 相对湿度不超过 80%。

4. 为了避免内窥镜在运输途中受损, 我们建议在送货和维修时使用原包装。

5. 器械及包装材料和附件的废弃处理, 应当遵守国家相关环保的规定。

### 13. High-frequency service parameter 高频使用参数

- 1) Operation mode: Cutting, clotting, cutting/clotting mix.
- 2) Output frequency: 1.7MHz ~ 4.0MHz.
- 3) Maximum output power:  $\leq 120W$ .
- 4) Maximum output voltage: cutting, cutting/coagulation mode  $\leq 600V$ , coagulation mode  $\leq 300V$ .
- 5) Warning: Avoid using explosive gases in areas where high-frequency endoscope attachments are used.
- 6) Safety type: I BF type.
- 7) Anti-fluid level: IPX7.

1. 操作模式: 切割、凝血、切割 / 凝血混合。
2. 输出频率: 1.7MHz ~ 4.0MHz。
3. 最大输出功率:  $\leq 120W$ 。
4. 最高输出电压: 切割、切割 / 凝血模式 $\leq 600V$ , 凝血模式 $\leq 300V$ 。
5. 警告: 在使用高频内窥镜附件的区域, 避免使用爆炸气体。
6. 安全类型: I类 BF 型。
7. 防进液等级: IPX7。

### 14. Date of Manufacture, & Expiration Date 生产日期及使用期限

Date of Manufacture: See product label

Lifetime: 5 years

Number of repetitions: 100 times

Note: The service life and the number of repeated use of the first to achieve the first.

生产日期: 见产品标签

使用期限: 五年













重复使用次数: 100次

注: 使用期限与重复使用次数先达到者为先。

### 15. Complications/Side Effects 并发症/副作用

- a. Nerve root injury 神经根损伤
- b. Infection 感染

### 16. Graphic symbol interpretation: 图形符号解释:

	BF type application part		Handle with care		Caution		Sterilization parameter
	Be afraid of rain		Model number		Date of manufacture		Batch Code
	Temperature limit		Humidity limitation		Use by date		The atmospheric pressure limit



Manufacturer



Consult instructions for use



Serial number



**Company Name :Lotus NL B.V.**

**Company Address:Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.**

**Tel: +31644168999**

**E-mail: [peter@lotusnl.com](mailto:peter@lotusnl.com)**