1Product Performance

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.

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.

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

2. Scope of application

Spinal Endoscope is used for imaging during spinal surgery.

3. Contraindication

○ Mental patients. ○ Pregnant women and others unfit for surgery.

4. Patient target group

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

5. Warning

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, 2% glutaraldehyde solution for sterilization 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 41ºC, 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.

Before each use, or after changing th

6. Safety tips

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.

7. Complications/Side Effects

a. Dural Tear

b. Nerve root injury

c. Infection

8. Graphic symbol interpretation:

 BF type application part  Handle with care  Caution

 Sterilization  parameter 

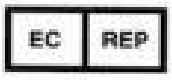
 Be afraid of rain Model number

Date of manufacture  Batch Code

 Temperature limit  Humidity li  tion Use by date

 The atmospheric pressure limit

 Manufacturer  Consult instructions for use  Serial number



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