

1、Brand: Single Use Sterile Laparoscopic Trocar Kit

2、Product information including:

2.1、Product Description:

The product consists of trocar needle, trocar cannula, choke valve, sealing cap, handle back cover and air injection valve. Composition, insufflation needle, specimen bag and stopper are optional components.

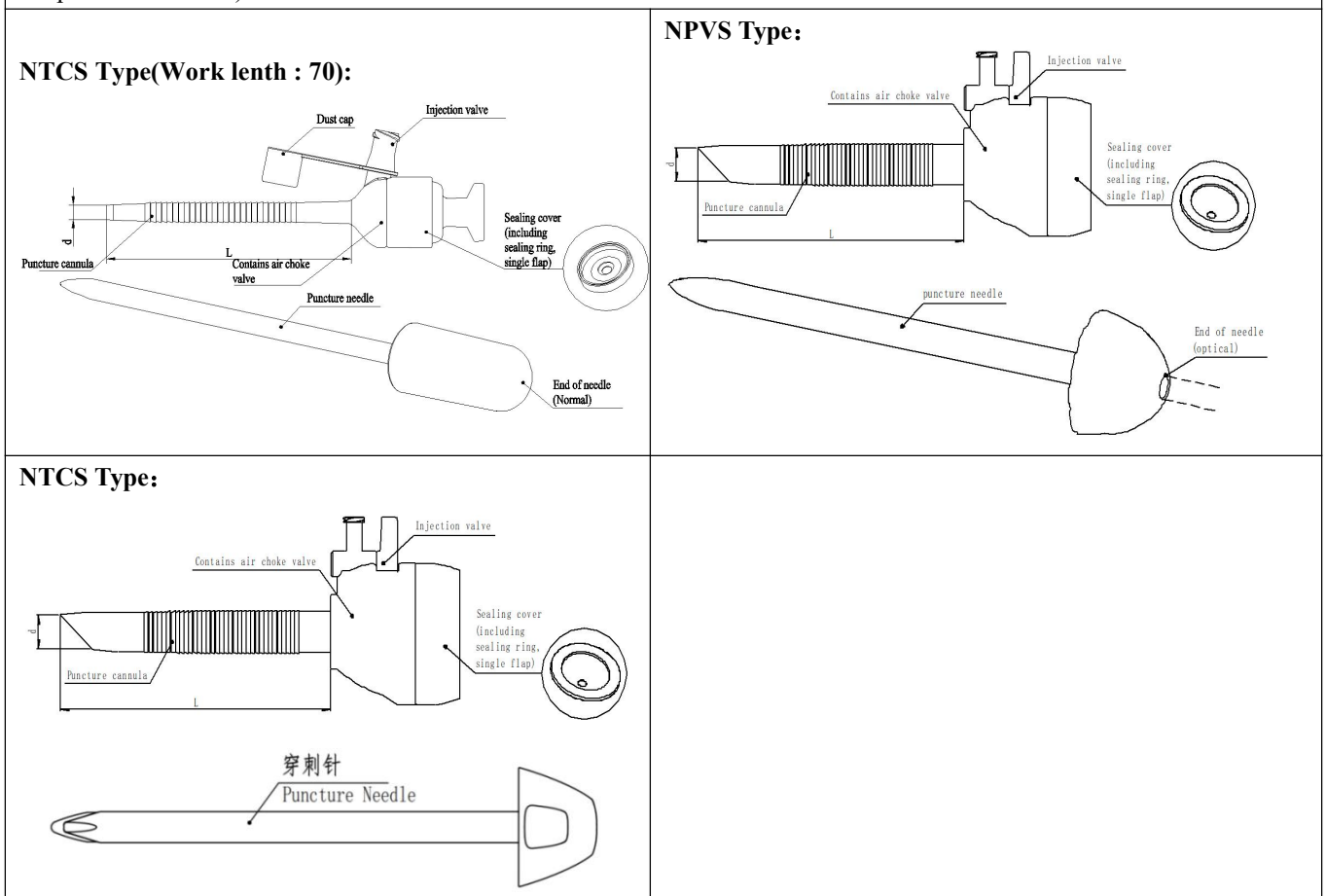
2.2、Models and Specification:

型号 Model	规格 Specification	
	长度 Length	配置 Configuration
NPVS、NTCS	70、100	1-3、1-5、1-10、1-12、1-15、2-A、2-B、2-C、2-D、3-A、3-B、3-C、3-D、3-E、4-A、4-B、4-C、4-D、5-A、5-B、5-C

2.3、Product structure:

穿刺器结构示意图如下所示，其中 d（穿刺套管内径）、L（穿刺套管工作长度）为管控尺寸。

The schematic diagram is shown as follows, in which d (inner diameter of the puncture cannula) and L (working length of the puncture cannula) are the controlled dimensions.



2.4 Use

2.4.1 Intended use

The product is a single-use auxiliary device for surgical treatment. It applies to puncturing human tissue during the process of the laparoscopic surgery and establishing a in-out passage for endoscope and surgical instruments. The filing valve of the puncture needle is supplied as a passage for transporting gas in the abdominal cavity. And it is intended for patients who undergo laparoscopic surgery.

2.4.2 Special use

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3、Indications

Is applicable for minimally invasive endoscopic surgery, providing the working channel for endoscopic instruments in and out of the incision and surgical passage.

4、Contraindications

1. Patients with severe cardiovascular disease, or with cardiac dysfunction, or with low lung function.
2. Patients with disturbance of blood coagulation, or with hematologic disease, or with predominant ascites, or with entorrhagia.
3. Patients with severe intestinal inflation, or with obesity, or with a history of several laparotomy.
4. Patients with obesity (BMI \geq 28) and history of multiple laparotomy are prohibited.

5、Warnings and Precautions

1. The product is aseptic, and it is prohibited to use after the expiration date of sterilization.
Please check the packaging before use. If any damage or contamination is found, it is strictly prohibited to use.

2. This product shall be used once, and shall not be reused or sterilized.

Re-use, re-treatment, or sterilization may impair the structural integrity of the device and/or cause device malfunction, resulting in injury, illness, or death of the patient.

Similarly, retreatment or sterilization of disposable devices may increase the potential for contamination and/or cause infection or cross-infection in patients, including but not limited to the transmission of infectious diseases from one patient to another.

Contaminated devices can cause injury, illness, or death to patients.

3. Minimally invasive surgery can only be performed by appropriately trained personnel with extensive experience in minimally invasive technology.

Before performing any minimally invasive surgery, consult the literature on surgical techniques, complications, and hazards.

4. The diameter of minimally invasive devices may vary slightly depending on the manufacturer.

When using minimally invasive instruments and accessories from different manufacturers in the same minimally invasive surgery, it is necessary to verify the compatibility of these instruments and accessories before the operation to prevent other minimally invasive instruments from becoming too large and causing puncture outfit cannula to burst.

5. The operator should fully consider that the compatibility between the size of the cannula and the size of the specimen should be paid attention to when taking out the postoperative specimen. If the specimen is too large, it should be first crushed and taken out to prevent the puncture device cannula rupture caused by violent pulling.

6. Despite the blunt design of the puncture, care should be taken to avoid damaging the great vessels and other anatomical structures (such as the intestine and mesentery) as with other puncture devices.

To minimize the risk of these injuries, it is necessary to:

When the abdomen is inflated, it must be sufficient;

Arrange the position of the patient reasonably so that the abdominal organs can be far away from the puncture area.

The tip of the puncture device should avoid large blood vessels and important anatomical structures.

Do not use excessive force.

Once fully inside the abdominal cavity, the minimally invasive puncture device should not be pushed forward.

It is possible to damage the intraperitoneal structure by pushing the minimally invasive puncture device at this stage.

Once a partial entry has been made, only a small amount of force is required to complete the full entry.

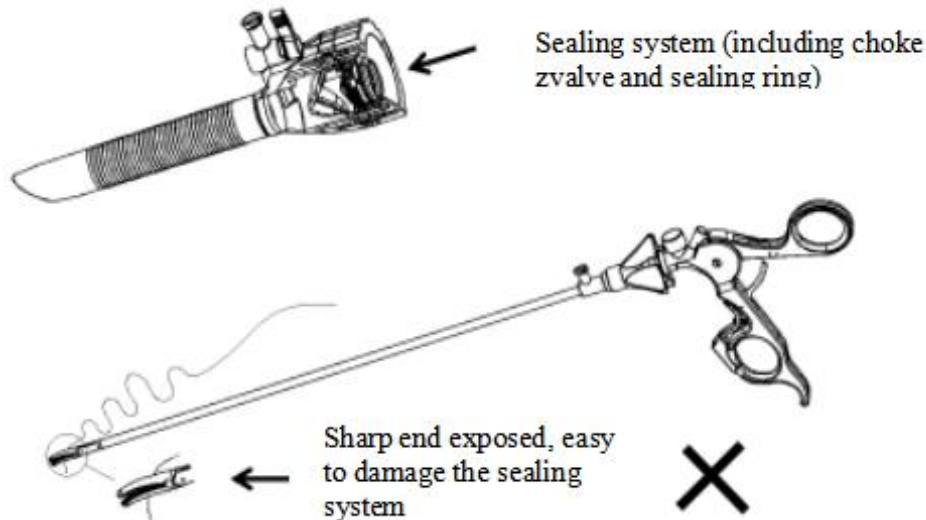
Excessive force can damage structures in the abdominal cavity.

7. If the diameter of the minimally invasive instrument is smaller than the required diameter of the minimally invasive puncture device, it will cause insufficient or leakage of air in the abdominal cavity. It is suggested that the instrument should be an instrument matching the diameter and specifications of the puncture cannula.

8. When importing or removing the instrument through the puncture outfit casing, care must be taken to avoid accidentally damaging the sealing system (including the choke valve and sealing ring) and causing abdominal air leakage.

When inserting sharp or angled endoscopic instruments with sharp edges, care should be taken to avoid

tearing the sealing system. For example, during the introduction or removal of needle and suture lines during surgery, the sharp end should be avoided from contacting the sealing system directly, so as to avoid causing damage to the sealing system or force shedding during operation of other instruments after damage.



9. The performer shall thoroughly understand the operation method of the endoscope stapler and the forceps used for endoscope, and avoid starting or activating the head of the instrument while it is still inside the casing, which may cause damage to the casing of the puncture device.

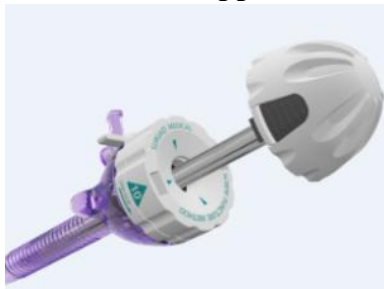
10. The performer should have a thorough understanding of the technical principles and operating methods of laser, electrosurgery and ultrasound so as not to cause harm to patients and medical staff by electrical injuries and burns, or damage to instruments or other medical devices.

Ensure that electrical insulation or grounding measures are foolproof.

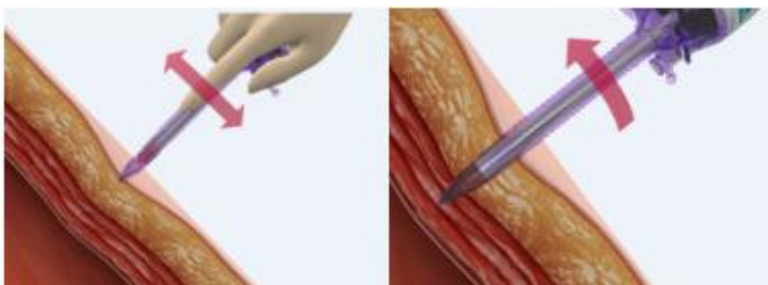
The electrosurgical instrument should not be inserted into the liquid unless the design and label indicate that it is invasive.

11. After taking out the minimally invasive puncture device from the abdominal cavity, it is necessary to check whether the puncture site has stopped bleeding thoroughly. If the bleeding is not complete, correct measures should be taken to stop the bleeding thoroughly.

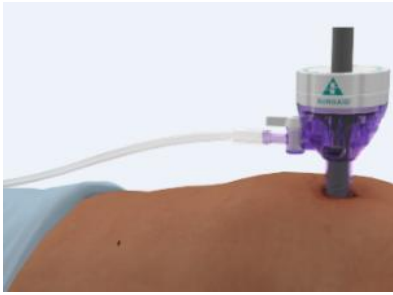
6、 Method of application



1. Remove the cannula and the puncture needle from the sterilized package and place it in a sterile work area. Insert the puncture needle into the cannula. Put the end cap in the palm during the puncture.



2. Hold the trocar handle, and then puncture into the abdominal cavity with left-right turning. And turn clockwise after the head into the abdominal wall.



3. Open the stopcock for ventilation during surgery.



4.1 Take out the needle. The cannula is used as the channel, and then performs the surgery.

4.2 If it is needed to remove the large tissue after the surgery, the sealed cap can be taken off, and remove the large tissue out from the cannula.

7、Material of main parts

主要部件 Main Part		材料 Material
Puncture Cannula 穿刺套管	Puncture Cannula 穿刺鞘管	PC、06Cr19Ni10
	Seal Cap 密封盖	ABS
	Air injection Valve 注气阀	PC+PE
Puncture Needle 穿刺针	Puncture Needle 穿刺针	PC、06Cr19Ni10

8、Shelf life

On the premise that the device is transported, stored and operated as guided, its shelf life is 2 years from the date of sterilization.

9、Sterilization

The trocar of Surgaid company is sterilized with ethylene oxide.

10. Maintenance and storage conditions

Keep the trocar properly. Collision and oppression should be avoided during storage and transportation. The packed trocar should be stored in a room with relative humidity no more than 80%, clean, dark, non-corrosive gas and good ventilation.

11、Manufacturer

Manufacturer:	Surgaid Medical (Xiamen) Co., Ltd.
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