Technical Data
Balloon Trocars

Compiled by	Reviewed by	Approved by
Martin Sun	David Cheng	David Cheng

Hangzhou Kangji Medical Instrument Co., Ltd.

1. Device description

Product name: Balloon Trocars

The Balloon Trocars design has an inflatable balloon that is mounted at the cannula tip. Once the cannula tip is positioned inside the patient's abdominal cavity, the balloon is inflated thus preventing the cannula from unintended movement out of the patient. To prevent unintended movement into the patient, a movable bolster/holder located on the cannula portion outside the patient is advanced until it contacts the patient's skin. The balloon/bolster combination - in effect - anchors the cannula to the abdominal wall, thus preventing undesirable shifting as the surgery proceeds. This is a single-use device.

The product was sterilized by EO. The sterility assurance level (SAL) is defined as 10^{-6}. The valid period of sterilization was 3 years.

2. Intended use

Balloon Trocars is surgical device intended to be percutaneously inserted through the abdominal wall to create an access port for laparoscopic instrument during laparoscopy. If needed, the CO_2 can be infused through its valve.

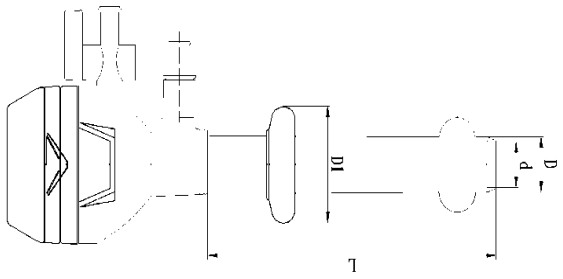
3. Classification Risk

In clinical use, the cannula and obturator tip contact with patient's abdominal wall subcutaneous tissue and abdominal mucosa and no more than 4h. According to the intended use of the product, it is determined that the product is a short-term surgically invasive device.

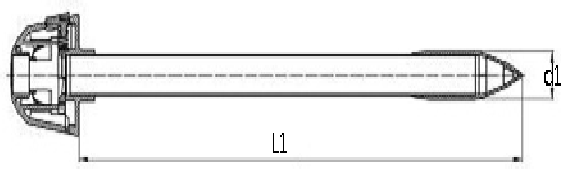
Classification Risk: According to MDD 93/42/EEC Annex IX Rule 7, the DISPOSABLE TROCARS belong to class IIa medical devices. According to MDR 2017/745 Annex VIII Rule 7, the Thoracic Cavity Trocars belong to class IIa medical devices.

4. Device specification

The specification of Balloon Trocars

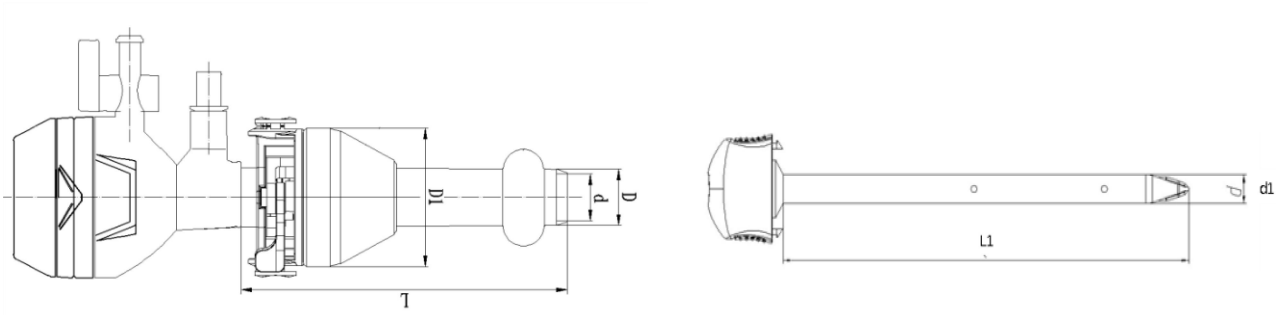


Cannula A



Obturator A

Technical Data	Balloon Trocars



Cannula B Obturator B

Fig. 1 Balloon Trocars

Table 1 Balloon Trocars A(mm)

Size	D	d	D1	L	d1	L1
Φ3	Φ8±1	Φ4±1	Φ25±5	55±10	Φ3.8±1.0	117±3
Φ5	Φ10±1	Φ6±1	Φ25±5	90±15	Φ5.8±1.0	156±3
Φ5S	Φ10±1	Φ6±1	Φ25±5	55±10	Φ5.8±1.0	117±3
Φ5L	Φ10±1	Φ6±1	Φ25±5	120±20	Φ5.8±1.0	190±3
Φ10	Φ14.5±1.0	Φ11±1	Φ30±5	90±15	Φ10.7±1.0	174±3
Φ10L	Φ14.5±1.0	Φ11±1	Φ30±5	140±20	Φ10.7±1.0	217±3
Φ12	Φ16.5±1.0	Φ13±1	Φ35±5	90±15	Φ12.7±1.0	175±3
Φ12L	Φ16.5±1.0	Φ13±1	Φ35±5	140±15	Φ12.7±1.0	226±3
Φ15	Φ20.0±1.5	Φ16.0±1.5	Φ35±5	90±15	Φ15.7±1.0	175±3

Table 2 Balloon Trocars B(mm)

Size	D	d	D1	L	d1	L1
Φ3	Φ8±1	Φ4±1	Φ32±5	55±10	Φ3.8±1.0	117±3
Φ5	Φ10±1	Φ6±1	Φ32±5	90±15	Φ5.8±1.0	156±3
Φ5S	Φ10±1	Φ6±1	Φ32±5	55±10	Φ5.8±1.0	117±3
Φ5L	Φ10±1	Φ6±1	Φ32±5	120±20	Φ5.8±1.0	190±3
Φ10	Φ14.5±1.0	Φ11±1	Φ38±5	90±15	Φ10.7±1.0	174±3
Φ10L	Φ14.5±1.0	Φ11±1	Φ38±5	140±20	Φ10.7±1.0	217±3
Φ12	Φ16.5±1.0	Φ13±1	Φ38±5	90±15	Φ12.7±1.0	175±3
Φ12L	Φ16.5±1.0	Φ13±1	Φ38±5	140±15	Φ12.7±1.0	226±3
Φ15	Φ20.0±1.5	Φ16.0±1.5	Φ38±5	90±15	Φ15.7±1.0	175±3

5. Storage condition

The device should be packaged with a suitable packaging. The store in the rooms with:

Relative humidity not exceed RH80%,

Temperature range -10℃ (14°F)up to +50℃(122°F),

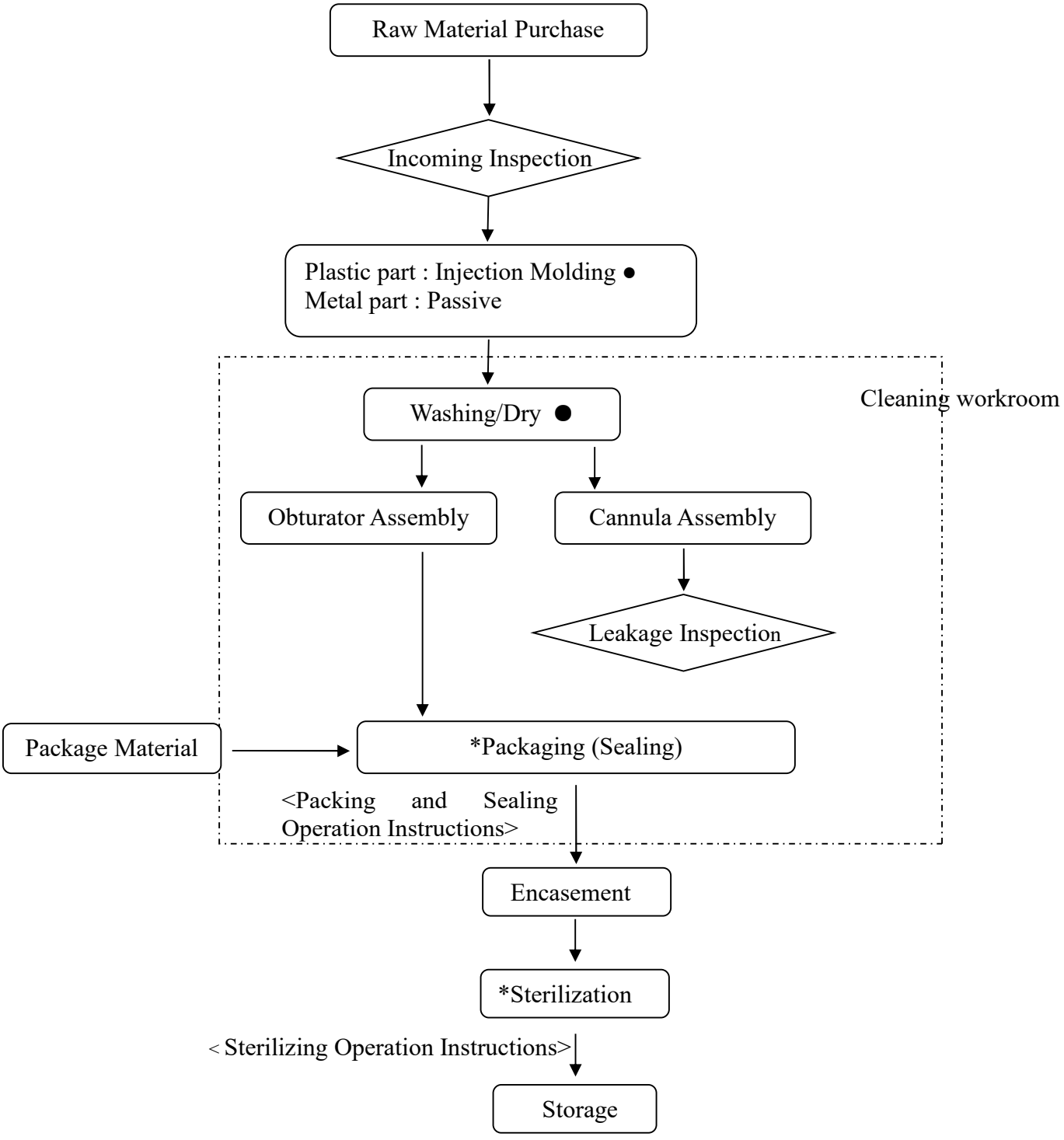
Atmospheric pressure range:760hPa～1060hPa,

Without sunshine directly, and no corrosive gas.

6. Raw material

Component		The raw materials	Supplier	Source	Other
Cannula	The cannula	PC	homemade	Bayer	Makolone 2858
	The valve body	PC	homemade	Bayer	Makolone 2858
	The valve core	PE	homemade	LG Chem Ltd.	ME9180
	Umbelliform gland bush	Polyisoprene	Fushun Yikesi New Material Co., Ltd	/	IR70F
	Cross-shaped gland bush	Silicone	Hangzhou Taishun seal Co.Ltd	/	Dow Corning C6-265
	Sealing Protector	TPU	homemade	Bayer	Desmopan W83095A DPS300
	Sealing System Cap	ABS	homemade	Chimei	PA-757
Obturator	blund Tip	ABS		Chimei	
	Optical Tip	PC	homemade	Bayer	Makolone 2858
	Tube Holder	ABS	homemade	Chimei	PA-757
Balloon Optical Trocar	Balloon	PVC	homemade	Jiangsu Dahai plastic Co., Ltd	CAS No.: 9002-86-2

7. Manufacturing Flowchart



Note: The special process marked with "*".
The key process marked with "●"

8. Packaging material

Model/Parts		The raw materials	Supplier	Source	Other
Package	Blister	APET	Suzhou Funway Plastic Co. Ltd.		
	Blister paper	Tyvek	Shanghai Pumao	Dupont	4058B