Shogun Axis™ Fascial Closure System

Instructions for Use

Shogun Medical Limited – Product Range					
Ref. No.	**Description**	**Size**	**Length**	**Pack**	**Pcs/ Box**
1018S	Fascial Closure System- Optical	10mm	180mm	1	6
1218S	Fascial Closure System- Optical	12mm	180mm	1	6
1518S	Fascial Closure System- Optical	15mm	180mm	1	6
1018B	Fascial Closure System- Bladeless	10mm	180mm	1	6
1218B	Fascial Closure System- Bladeless	12mm	180mm	1	6
1518B	Fascial Closure System- Bladeless	15mm	180mm	1	6

Please read all instructions thoroughly prior to use. Improper use or failure to follow these directions may result in serious surgical complications.

Note: This insert provides guidance on the proper use of the Shogun Axis™ Bladeless and Optical Fascial Closure Systems. It is not intended as a training resource for trocar insertion techniques.

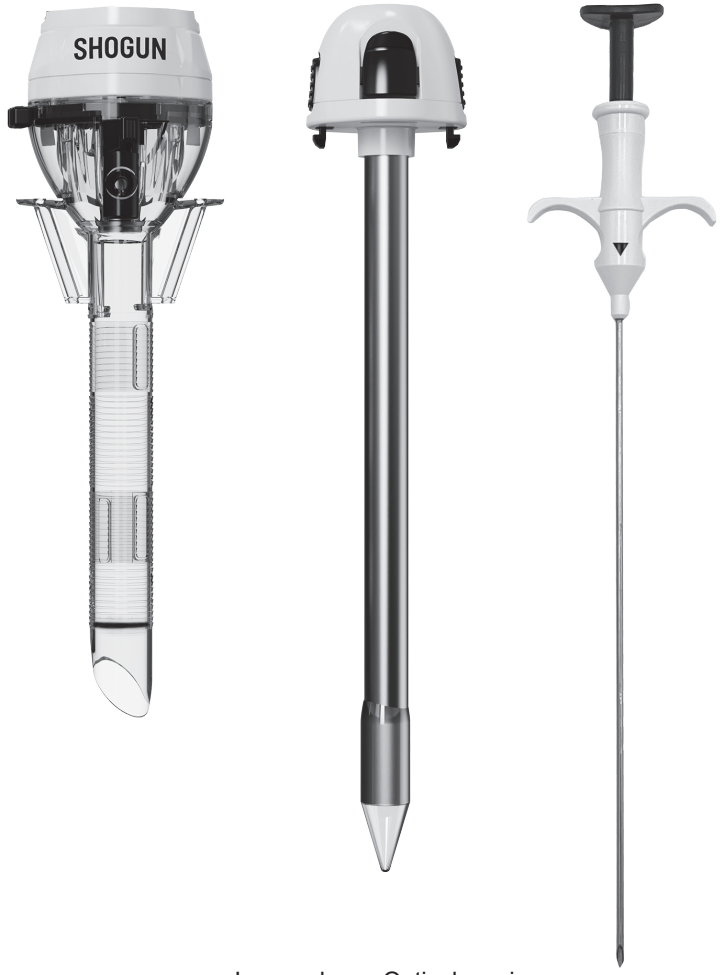


Image shows Optical version

1. Device Description

The Shogun Axis™ Fascial Closure System is a sterile, single-use surgical device used to gain laparoscopic access and assist in fascial closure.

It consists of:

Transparent cannula with seal **(see Fig. A),** insufflation port (i), and two suture channels (ii) (180° apart).

- A black alignment line near the base indicates proper positioning for suture placement (iii).
- Obturator (Optical or Bladless) **(see Fig. B with locking clamp (iv)**.
- Suture passer needle with push-button activation and directional markers **(see Fig. C)**.

Fig. A

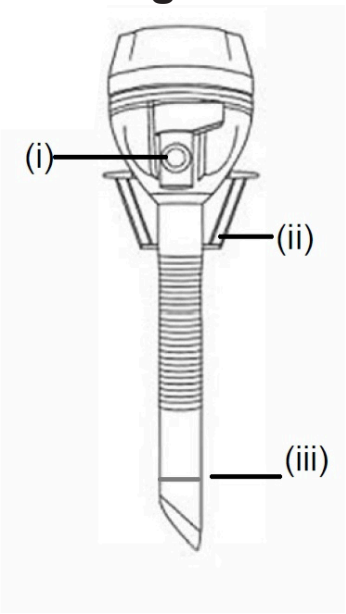


Fig. B

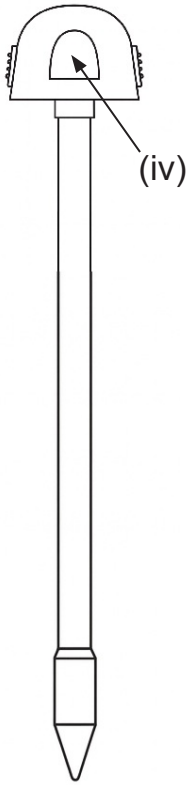
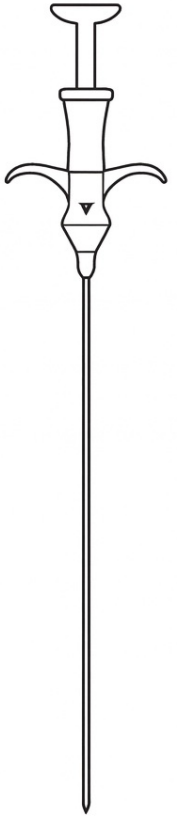


Fig. C



2. Indications for Use

The Shogun Axis™ Fascial Closure System is intended for use in adult patients undergoing laparoscopic procedures, including:

- General surgery
- Gynecologic surgery
- Urologic procedures
- Thoracic surgery
- Other endoscopic procedures requiring port-site closure

The device is used to:

- Penetrate the abdominal wall under direct visualization (Optical version only).
- Establish and maintain laparoscopic access ports.
- Facilitate fascial closure of trocar sites ≥10 mm using integrated suture channels.
- For use only by surgeons trained in adult laparoscopic or endoscopic surgery.

3. Contraindications

Active infection at the intended insertion site.
Patient conditions where laparoscopic/endoscopic surgery is contraindicated.
Individual patient risks as determined by the physician.

4. Warnings and Precautions

General:

- Verify compatibility of all instruments and accessories prior to using the instrument
- Prepare the patient in accordance with proper surgical techniques prior to insertion of the trocar
- Single-use only. Do not reuse or re-sterilize.
- Use only under direct laparoscopic vision to avoid visceral or vascular injury (Optical version only).
- Do not use if the packaging is damaged or sterility compromised.
- Ensure pneumoperitoneum is established before secondary port use.
- Inspect all components for integrity prior to use and monitor during use.
- Closure-Specific:
- Do not force the suture passer. If resistance is encountered, reassess position.
- Always perform fascial closure under visualization.
- Avoid contact with sharp or energized instruments.
- During removal of the cannula, maintain orientation and tissue stability to prevent suture disruption
- Confirm hemostasis before attempting closure.

5. Instructions for Use

5.1 Preparation and Assembly

Inspect Packaging Integrity

Before use, carefully inspect all packaging for signs of damage. This includes a thorough check of the sterile barrier system for any breaches or compromise in package integrity.

Caution: Do not use the product if the sterile barrier or outer packaging is damaged or compromised in any way.

Opening the Package

Using sterile technique, remove the instrument from its packaging.

Important: To prevent damage, do not toss or flip the instrument into the sterile field.

The trocar obturator and cannula sleeve are supplied unassembled. To assemble:

a. Remove and discard the protective tip cover from the obturator.

b. Insert the Obturator fully into the Cannula **(see Fig. D)** until an audible ‘click’ is heard, indicating proper engagement. **(see Fig. E)**.

The device is packaged with the stopcock in the ***open*** position.

Before use, rotate the stopcock lever to the closed position. The stopcock is ***closed*** when the lever is aligned parallel to the sleeve. **(see Fig. E (v)**.

Fig. D

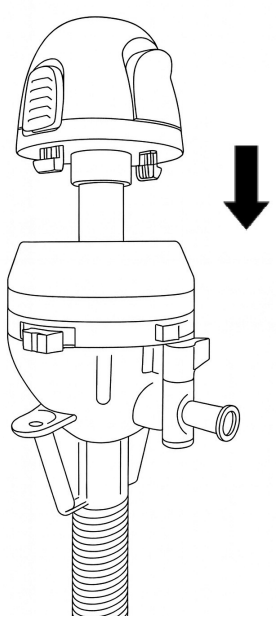
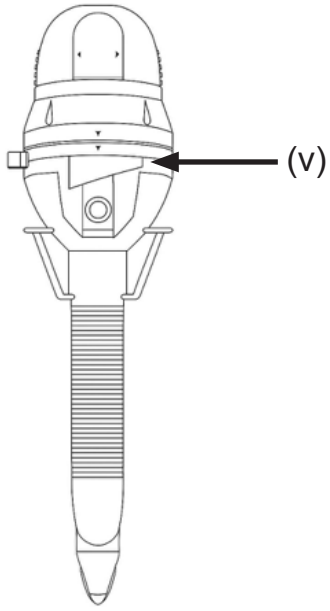


Fig. E



5.2 Insertion With Endoscope

Follow the steps below for the 10,12 and 15mm Optical Trocar using an endoscope

Make a skin incision of appropriate size, using appropriate surgical procedure.
Insert a 0° laparoscope into the opening at the proximal end of the obturator until it reaches the distal tip of the optical section **(see Fig. G)**.
Rotate the endoscope as desired.
Secure the endoscope in the obturator using the scope locking clamp. **(see Fig. F).**
Advance the trocar through the abdominal wall using gentle, controlled force while visualizing the tissue layers **(see Fig. G)**.

Fig. F

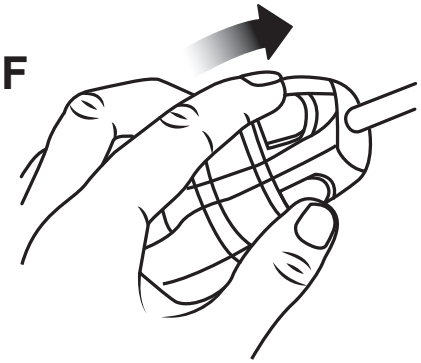
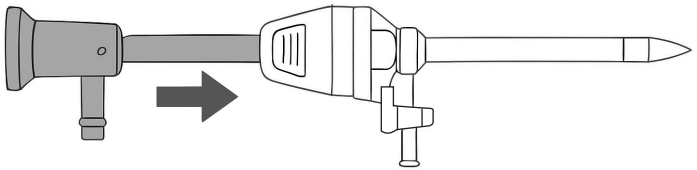


Fig. G



5.2.1 Obturator and Endoscope Removal

Once the trocar is properly positioned within the abdominal or thoracic cavity, press the release buttons on the obturator to disengage and withdraw both the obturator and the endoscope **(see Fig. I)**. This leaves the trocar sleeve securely in place. To separate the endoscope from the obturator, release the scope locking clamp and carefully remove the endoscope. As the obturator is withdrawn, the sleeve's internal valve system automatically seals, helping to preserve insufflation even when no instrument is present in the lumen.

5.2.2 Insertion Without Endoscope:

Follow the steps below for the 10,12 and 15mm Bladeless Trocar (without the use of an endoscope)

Make a skin incision of appropriate size, using appropriate surgical procedure. Advance the trocar through the abdominal wall using gentle, controlled force. **(see Fig. H)**.

5.2.3 Obturator Removal

Once the trocar is properly positioned within the abdominal or thoracic cavity, press the release buttons on the obturator **(see Fig. I)** to disengage and withdraw the obturator. This leaves the trocar sleeve securely in place. As the obturator is withdrawn, the sleeve's internal valve system automatically seals, helping to preserve insufflation even when no instrument is present in the lumen.

Fig. H

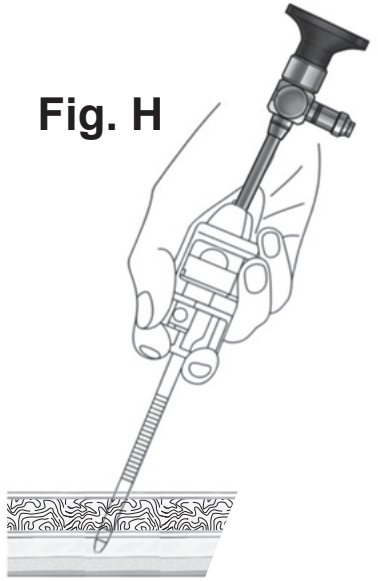
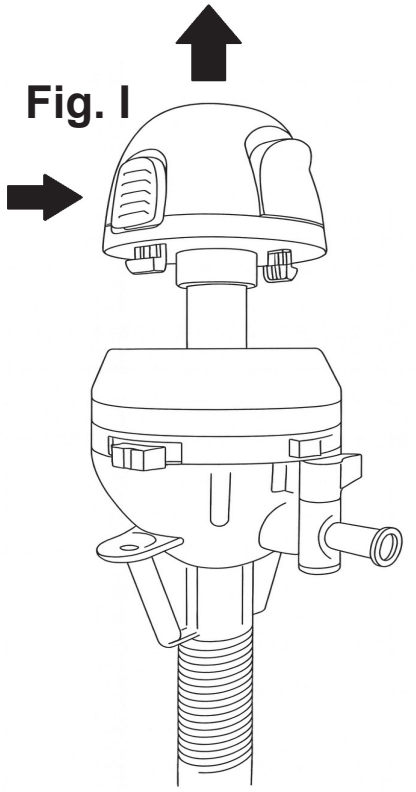


Fig. I



5.2.4 Insufflation

If insufflation is required, connect the insufflation tubing to the gas inlet twist luer port **(see Fig. K vi)**, open the stopcock tap by rotating and begin insufflation per hospital protocol **(see Fig. K vii)**. Monitor intra-abdominal pressure using standard laparoscopic equipment.

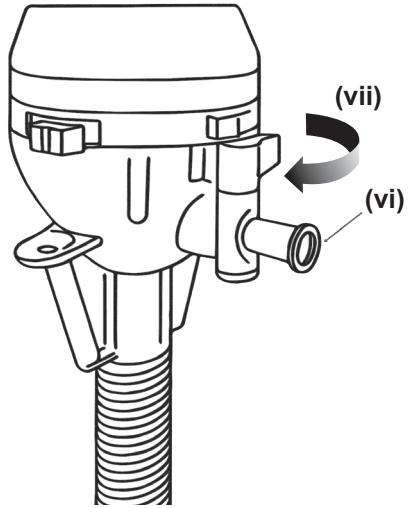


Fig. K

5.3 Instrument Access

Insert laparoscopic instruments through the cannula, as needed.

Ensure seal integrity is maintained.

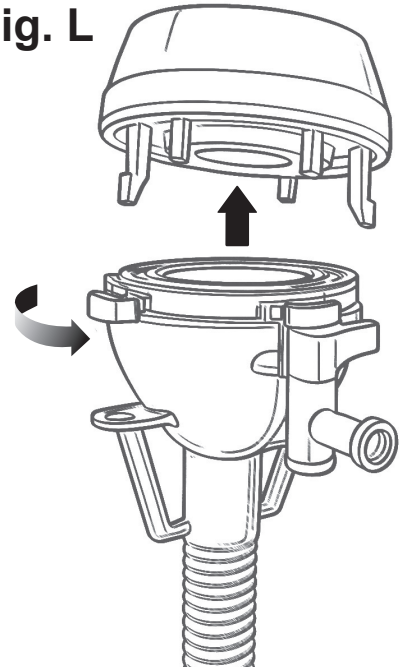
Do not insert sharp instruments without protective tips.

5.4 Specimen Retrieval

For all trocar sizes, the outer seal can be temporarily removed to facilitate specimen extraction. To remove the seal:

- Rotate the outer seal release lever counterclockwise **(see Fig. L)**
- Lift the seal assembly off the top of the trocar.
- After the specimen is retrieved, reattach the outer seal by:
- Aligning the reducer cap with the top of the trocar.
- Ensuring the seal latches are positioned over the corresponding attachment points.
- Pressing down until the cap audibly clicks into place.

Fig. L



5.5 Fascial Closure

After removing the obturator, position the cannula so that the black alignment line on the shaft is flush with the internal surface of the peritoneum. This ensures correct depth for safe fascial closure **(see Fig. M).**

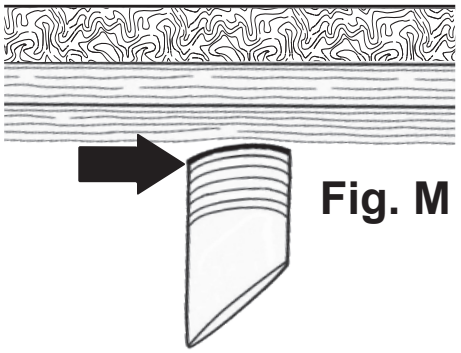
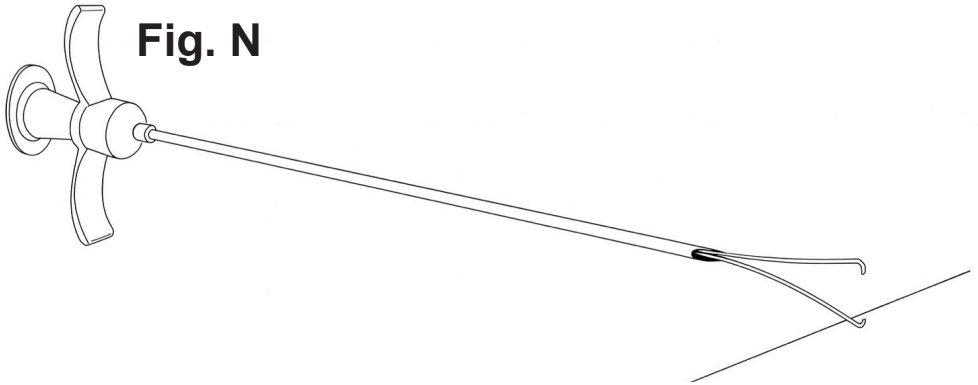


Fig. M

5.5 Loading the Suture Passer

1. Remove and discard the protective tip cover.
2. Depress the top button of the provided suture passer to open the grasping jaws.
3. Load the suture into the open jaws of the suture passer **(see Fig. N).**
4. Release the button to securely grasp the suture.
5. Insert the suture passer through one of the closure channels, ensuring the black arrow is facing outward **(see Fig. P)**

Fig. N



Advance through the first cannula seal, the fascia and peritoneum under direct vision **(see Fig. O);** release the suture into the abdominal cavity before withdrawing the suture passer.

Use a laparoscopic grasper (via another access port) to reposition the suture loop, if necessary.

Fig. O

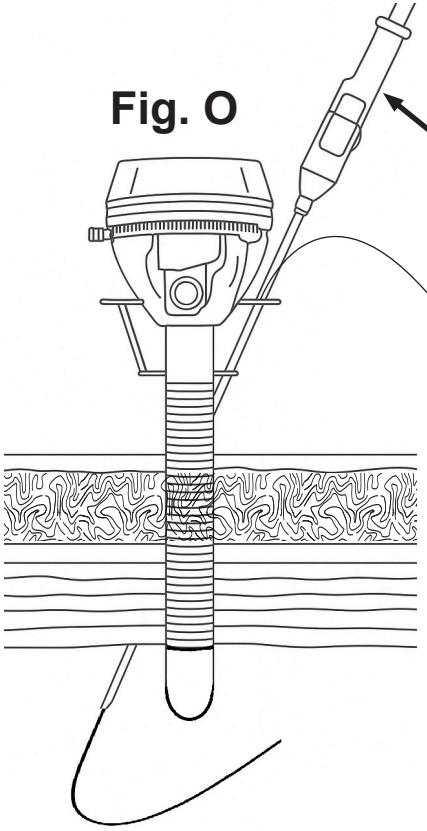
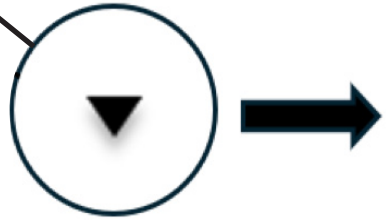


Fig. P



Insert the suture passer through the opposite suture channel to capture and retrieve the suture by pulling up through the peritoneum, muscle, fascia, and finally through the suture channel **(see Fig. Q).**

Detach the gas line and open the stopcock to allow rapid venting of gas from the cavity.

Withdraw the cannula while securing both ends of the suture **(see Fig. R).**

Tie the suture extracorporeally.

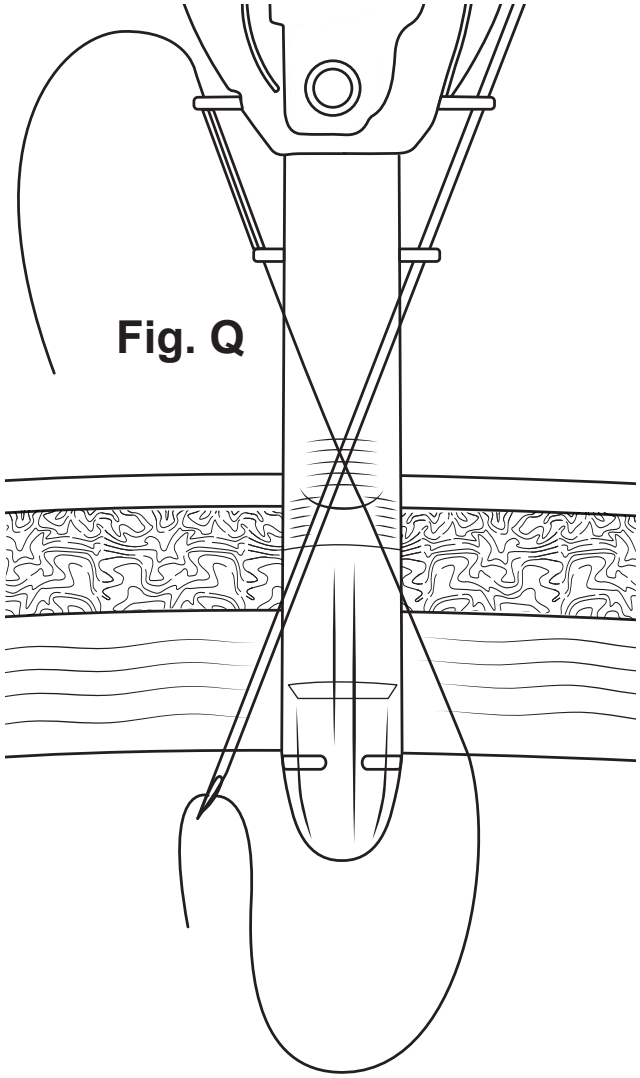


Fig. Q

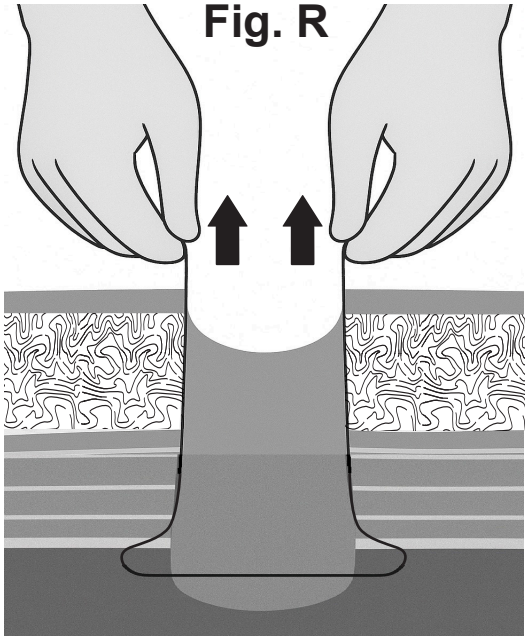


Fig. R

6. Storage and Handling

Store in a dry, clean environment at ambient temperature. Avoid direct sunlight and moisture. Keep in original packaging until use.

7. Disposal

Dispose of the device in accordance with hospital protocols and local regulations for biohazardous medical waste.

8. Residual Risks

Despite correct usage, possible risks include:

- Organ or vessel injury
- Bleeding
- Incomplete fascial closure
- Infection or foreign body reaction to suture material

9. Symbols Glossary

EXPLANATION OF SYMBOLS			
REF	Catalogue Number		Distributor
LOT	Batch Code		Do not use if package is damaged
	Expiry Date		Caution
STERILE EO	Sterilized using Ethylene Oxide		Do not resterilize
	Do not re-use		Not made with natural rubber latex
	Consult instructions for use	R_xOnly	CAUTION: U.S Federal law restricts this device to sale by or on the order of a physician
	Manufacturer		

Worldwide Distributor:
Shogun Medical Ltd, Hunter House,
150 Hutton Road, Shenfield, Essex CM15 8NL
United Kingdom
www.shogunmedical.com

Made in China

Manufacturer:
Suzhou Shenyun Medical Equipment Co., Ltd,
Building 11, No. 666, Yinzang Road, Linhu Town,
Wuzhong District, Suzhou City, Jiangsu, China

Imported by:
USA Corp XYZ
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