Puncture Kits User Manual

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EDGE MEDICAL

Puncture Kits

User Manual

www.edgemedicalrobotics.com

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Important Regulatory Information

Contact Information

For Customer Service and Reporting of Complaints or Adverse Events

During the use of the puncture kits, if a serious incident has occurred, it shall be reported to the manufacturer and/or its authorized representative and to competent authority.

Use the following information for customer service, including ordering, reporting complaints or adverse events, general information regarding Edge Medical or our products and services, if the puncture kits require maintenance or service. Preventive maintenance is required and must be performed by authorized Edge Medical personnel.

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Disclaimers

The company reserves the right of final interpretation of this document.

All figures provided in this document are for reference only, and the settings or parameters in the figures may not be exactly same as the products.

The company shall be responsible for the safety, reliability and performance of the products only if all of the following requirements are met:

- Assembly operation, extensions readjustment, improvement and maintenance are carried out by professionals approved by the company.
- All replaceable parts, accessories and consumables involved in maintenance are original or approved by the company.
- The electrical equipment complies with local standards and the requirements of this document.
- Carry out product operations according to this document.
- Any future changes to this manual may be updated without notice. If necessary, contact the manufacturer or your local representative for a copy.

About This Manual

Thank you for choosing the puncture kits. The manual provides feature descriptions and operating instructions of the puncture kits. Please read the manual carefully before using, and keep the manual properly after reading.

Documentation Conventions

Symbol	Description
	**Note:** Indicates important information.
	**Caution:** Indicates situations that could cause equipment damage.
	**Warning:** Indicates situations that could cause personal injury or even death.

Table of Contents

1. Introduction

This manual provides instructions for the puncture kits.

Note: Do follow all instructions provided with the applicable user manuals for the endoscopic instrument control system, instruments and accessories not included in this manual.

1.1 Product Components

The puncture kits consist of reducers, cannulas, obturators and cannula seals.

Device Name	Product Name	Model
Cannula	Cannula	TR1-A8I
	Cannula	TR1-A8E
	Cannula	TR1-A12
	Cannula	TR1-A15
	Long Cannula	TR1-A8I-L
	Long Cannula	TR1-A8E-L
	Long Cannula	TR1-A12-L
	Long Cannula	TR1-A15-L
Obturator	Blunt Obturator	TR2-A8IB
	Blunt Obturator	TR2-A8EB
	Blunt Obturator	TR2-A12B
	Blunt Obturator	TR2-A15B
	Prismatic Obturator	TR2-A8IP
	Prismatic Obturator	TR2-A8EP

Device Name	Product Name	Model
	Prismatic Obturator	TR2-A12P
	Prismatic Obturator	TR2-A15P
	Long Blunt Obturator	TR2-A8IB-L
	Long Blunt Obturator	TR2-A8EB-L
	Long Blunt Obturator	TR2-A12B-L
	Long Blunt Obturator	TR2-A15B-L
	Long Prismatic Obturator	TR2-A8IP-L
	Long Prismatic Obturator	TR2-A8EP-L
	Long Prismatic Obturator	TR2-A12P-L
	Long Prismatic Obturator	TR2-A15P-L
Cannula seal	Cannula Seal	TR3-A8
	Cannula Seal	TR3-A8E
	Cannula Seal	TR3-A12
	Cannula Seal	TR3-A15
Reducer	Reducer	TR4-A8/5
	Reducer	TR4-A12/8
	Reducer	TR4-A15/8

1.2 Intended Purpose/Indication for Use

The puncture kits are intended to pierce tissues and create surgical working channels during urologic surgical procedures, general laparoscopic surgical procedures, gynecologic laparoscopic surgical procedures, and thoracoscopic surgical procedures.

See Appendix B Intended Purpose Statements for detailed use of each component.

Caution: The puncture kits are designed and manufactured for a specific surgical function. Using the puncture kits for a task other than that for which it is intended may result in damage or breakage.

1.3 Intended User

The puncture kits are intended for use by physicians in an operating room environment who have the appropriate specialized qualifications in accordance with the representative specific procedures set forth in the professional instruction for use and have been trained in the use of the puncture kits by Edge Medical.

1.4 Intended Patient Population

The puncture kits are intended for adult patients suitable for urologic surgical procedures, general laparoscopic surgical procedures, gynecologic laparoscopic surgical procedures, and thoracoscopic surgical procedures. Patient general health and medical history must be adequately assessed along with potential benefits and risks prior to performing procedures with the puncture kits.

1.5 Training

Warning: Only trained users and those who have developed adequate skills should use the puncture kits. Training provided by the company is limited to the use of the puncture kits and does not replace the necessary medical training and experience required to perform surgery.

1.6 Safety Information

The puncture kits are intended to be used by trained physicians in an operating room environment according to the specific instructions in this manual. Please read all instructions of safety information carefully. Failure to properly follow the instructions, cautions and warnings related to the instrument may result in serious injury or surgical complications to the patient. While these instructions appear throughout the manual, this chapter provides some general precautions.

1.6.1 Contraindications

Any and all relative and absolute contraindications to endoscopic, thoracoscopic and laparoscopic surgical techniques applicable to the use of conventional endoscopic surgical instruments apply to the use of the puncture kits. These puncture kits are not intended for use when endoscopic techniques are contraindicated.

1.6.2 General Precautions

Warning: Do not modify the puncture kits without authorization. Doing so may cause irreversible injury to the patient and medical personnel.

Warning: Do not use the puncture kits with visible cracks or other damage. Doing so may cause irreversible injury to the patient.

Warning: Failure to establish and maintain proper pneumoperitoneum in abdominal surgery may reduce available space and injure tissue inside or outside the field of view.

Warning: The integrity of the puncture kits should be checked before and after use to avoid damage during use and debris left inside the patient.

Warning: Check the port sites throughout surgery for forces on the patient at the remote center to prevent patient harm.

Caution: Be careful when inserting or removing the instruments with sharp edges or tips to avoid damage to the puncture kits.

Caution: To minimize the risks associated with port placement, ensure the following:

- Appropriate patient positioning to shift organs away from the port placement site.
- An adequate level of insufflation.
- Obturator tip is pointing away from major vessels, organs, and other anatomic structures.
- If possible, visualization of the entire insertion of the cannula using the endoscope is preferred.

- Utilize continuous, controlled pressure with a deliberate rotating motion when placing the cannula and obturator.

Note: Always have the appropriate backup available to complete the surgical procedure in case of device failure.

Note: The puncture kits listed in this manual are compatible with the endoscopic instrument control system.

1.6.3 Cannulas

Warning: The cannula must be used in conjunction with the appropriate cannula seal in order to maintain pneumoperitoneum. Do not insert instruments through the cannula that has external diameter less than the cannula seal diameter. Doing so may cause release of gas and loss of pneumoperitoneum.

Warning: The instrument diameter should match the cannula diameter. Otherwise, there is a risk of gas leakage or the instrument cannot move smoothly in and out of the cannula.

Warning: Ensure that the cannula outlet is not inadvertently blocked by patient anatomy, other instruments ports, kinked tubing, etc.

Warning: Do not use a damaged cannula. The damaged cannula may abrade the instrument shaft and generate particles that may fall inside the patient.

Warning: Remove all accessories before cleaning. Failure to remove may result in incomplete cleaning and sterilization.

Warning: The status, performance and integrity should be inspected before and after use for no rough surfaces, sharp edges or protrusions occurred on the cannulas. Do not leave any defected or damaged parts in the patient.

Warning: Do not remove the cannula and instrument from the body simultaneously as this may damage the surrounding tissues and the instrument.

Warning: Do not use a double cannula (installing one cannula into a larger cannula) on the endoscopic instrument control system as this may cause instrument damage

or an imbalance of the remote center, and potential injury to the patient.

Warning: Always straighten the instrument wrist before inserting or removing the instrument through the cannula. Do not use excessive force when inserting or removing instrument.

Caution: A skin incision that is too short will inhibit rotation of the cannula and increase resistance to insertion. Too large skin incision will increase instability.

Caution: The cannulas are designed with different lengths and diameters. Consider the length and diameter when placing ports to prevent inability to access target anatomy.

Note: Reusable cannulas are shipped non-sterile and should be cleaned and sterilized thoroughly before first use and after every use. Refer to the Accessories Reprocessing Instructions Manual for detailed instructions.

Note: Clean and sterilize the cannulas immediately after each use. Do not allow debris to dry on or inside the cannulas intraoperatively before processing.

1.6.4 Cannula Seals and Reducers

Warning: The cannula seals and reducers are provided in sterile packaging and are intended for single use. Reprocessing and/or reuse may result in degraded performance or loss of functionality, and in exposure to viral, bacterial, fungal, or prion pathogens.

Warning: To ensure the operating environment keep sterile, do not use the cannula seals or reducers if its package is open or damaged.

Warning: A breach in the sterile packaging indicates possible contamination. Do not use the cannula seals or reducers if packaging is not intact.

Warning: Ensure that the cannula seal outlet is not inadvertently blocked by patient anatomy, other instruments ports, kinked tubing, etc.

Note: Do not remove the cannula seal when removing the obturator or reducer to avoid unexpected loss of insufflation.

1.6.5 Obturators

Warning: Follow the instructions to install the obturator to a cannula and seal assembly and ensure complete attachment. Otherwise, incomplete attachment and unexpected detachment from the cannula may occur.

Warning: The status, performance and integrity should be inspected before and after use for no rough surfaces, sharp edges or protrusions occurred on the obturators. Do not leave any defected or damaged parts in the patient.

Note: Reusable obturators are shipped non-sterile and should be cleaned and sterilized thoroughly before first use and after every use. Refer to the Accessories Reprocessing Instructions Manual for detailed instructions.

Note: Clean and sterilize the obturators immediately after each use. Do not allow debris to dry on or inside the obturators intraoperatively before processing.

1.7 Symbol Reference Table

Symbol	Meaning	Symbol	Meaning
	Caution (consult instructions for use)		Do not use if package is damaged and consult instructions for use
	Do not re-use		Do not re-sterilize
STERILE EO	Sterilized using ethylene oxide		Consult instructions for use
LOT	Lot number	SN	Serial number
CE 0123	CE mark	8	Diameter size indicator of 8 mm
12	Diameter size indicator of 12 mm	15	Diameter size indicator of 15 mm
	For endoscopes	MD	Medical device

Symbol	Meaning	Symbol	Meaning
	Direction indicator for alignment		Direction indicator for rotation
8−5	Diameter size indicator of 8 mm-5 mm reducer	12−8	Diameter size indicator of 12 mm-8 mm reducer
15−8	Diameter size indicator of 15 mm-8 mm reducer	A/ B	Diameter size indicator of cannula accessory
	Manufacturer		Date of manufacture
	European authorized representative		Single sterile barrier system with protective packaging inside
	Use-by date		Temperature limit
	Humidity limitation		Atmospheric pressure limitation
	This way up		Fragile, handle with care
	Keep dry		Keep away from sunlight
	Stacking limit by number	/	/

1.8 Lifetime/Shelf Life

The cannulas and obturators are reusable accessories and should be reprocessed in accordance with the Accessories Reprocessing Instructions Manual, which has been validated for 500 cycles of use.

The cannula seals, reducer are intended for single use only and have an expected shelf life of 2 years. When accessories expire, they can no longer be used.

1.9 Date of Manufacture

See product label for date of manufacture.

2. Product Overview

2.1 Cannulas, Obturators and Cannula Seals

2.1.1 Introduction

The cannulas, obturators and cannula seals are intended to be used to establish a port of entry for instruments and endoscopes. The obturator attaches to the cannula seal, which attaches to the cannula and facilitates the cannula into the body cavity. The cannulas are available in different lengths and diameters, the obturators have various tip configurations for different mechanisms by which to enter the body cavity.

- A cannula is a tube with a lumen that provides a single port of entry into the body cavity for an instrument or an endoscope. The cannula fin is used for cannula docking.

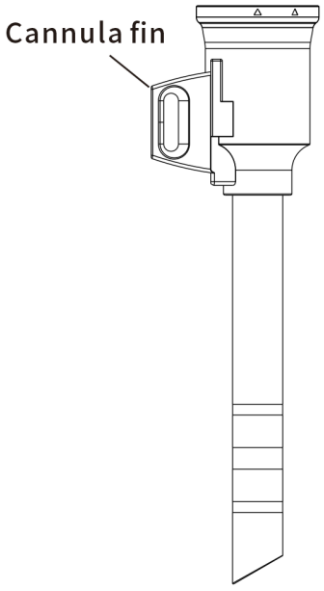
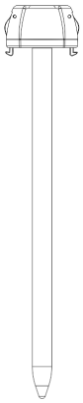


Figure 2.1 Cannula

- An obturator is a cylinder used when inserting the cannula into the patient to avoid coring or tearing of the body wall upon insertion. It should be removed before inserting an instrument or an endoscope through the cannula.

Obturator	Figure	Obturator	Figure
TR2-A8EB, Blunt Obturator TR2-A8EB-L, Long Blunt Obturator		TR2-A8EP, Prismatic Obturator TR2-A8EP-L, Long Prismatic Obturator	
TR2-A8IB, Blunt Obturator TR2-A8IB-L, Long Blunt Obturator		TR2-A8IP, Prismatic Obturator TR2-A8IP-L, Long Prismatic Obturator	
TR2-A12B, Blunt Obturator TR2-A12B-L, Long Blunt Obturator		TR2-A12P, Prismatic Obturator TR2-A12P-L, Long Prismatic Obturator	
TR2-A15B, Blunt Obturator TR2-A15B-L, Long Blunt Obturator		TR2-A15P, Prismatic Obturator TR2-A15P-L, Long Prismatic Obturator	

- A cannula seal is a sterile disposable cap for a cannula. It is used to maintain insufflation before inserting an instrument or an endoscope or during endoscopic surgery.

The cannula seal consists of an insufflation lever and an insufflation port to provide an outlet for insufflation or smoke evacuation. When the lever is straight and in line with the port, the lever is in open position. When the lever is perpendicular with the port, the lever is in closed position.

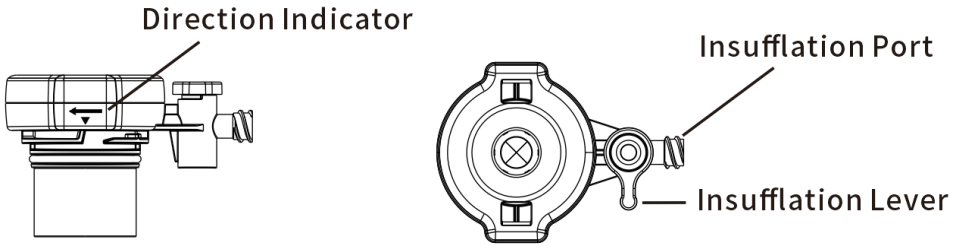


Figure 2.2 Cannula Seal

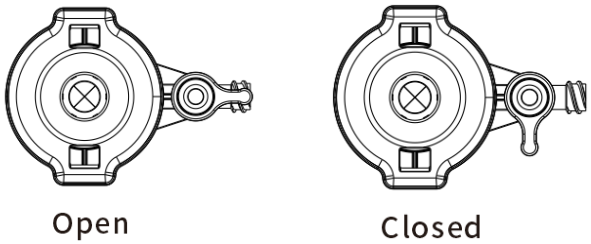


Figure 2.3 Open and Closed Insufflation Port

2.1.2 Compatibility Information

8 mm Cannulas, Obturators and Cannula Seals

- Cannulas (model TR1-A8I/TR1-A8I-L) for instruments are compatible with laparoscopic instruments with a diameter range of 8 mm to 9.4 mm.
- Cannulas (model TR1-A8E/TR1-A8E-L) for endoscopes are compatible with laparoscopic instruments with a diameter range of 8 mm to 10.8 mm.

Cannula	Obturator	Cannula Seal	Compatible Laparoscopic Instruments
TR1-A8I, Cannula	TR2-A8IB, Blunt Obturator TR2-A8IP, Prismatic Obturator	TR3-A8, Cannula Seal	8 mm Instruments
TR1-A8I-L, Long Cannula	TR2-A8IB-L, Long Blunt Obturator TR2-A8IP-L, Long Prismatic Obturator		
TR1-A8E, Cannula	TR2-A8EB, Blunt Obturator TR2-A8EP, Prismatic Obturator	TR3-A8E, Cannula Seal	Endoscopes

Cannula	Obturator	Cannula Seal	Compatible Laparoscopic Instruments
TR1-A8E-L, Long Cannula	TR2-A8EB-L, Long Blunt Obturator TR2-A8EP-L, Long Prismatic Obturator		

12 mm Cannulas, Obturators and Cannula Seals

Cannulas (model TR1-A12/TR1-A12-L) are compatible with laparoscopic staplers with a diameter range of 10.5 mm to 14.2 mm.

Cannula	Obturator	Cannula Seal
TR1-A12, Cannula	TR2-A12B, Blunt Obturator TR2-A12P, Prismatic Obturator	TR3-A12, Cannula Seal
TR1-A12-L, Long Cannula	TR2-A12B-L, Long Blunt Obturator TR2-A12P-L, Long Prismatic Obturator	

15 mm Cannulas, Obturators and Cannula Seals

Cannulas (model TR1-A15/TR1-A15-L) are compatible with laparoscopic staplers with a diameter range of 10.5 mm to 15.4 mm.

Cannula	Obturator	Cannula Seal
TR1-A15, Cannula	TR2-A15B, Blunt Obturator TR2-A15P, Prismatic Obturator	TR3-A15, Cannula Seal
TR1-A15-L, Long Cannula	TR2-A15B-L, Long Blunt Obturator TR2-A15P-L, Long Prismatic Obturator	

2.2 Reducers

2.2.1 Introduction

A reducer is a sterile, disposable, hollow cylinder with integrated seal. Before inserting a reducer through the cannula, remove the obturator. An instrument cannot be used until a reducer attaches to the cannula.

- Reducer (model TR4-A8/5) is inserted into the 8 mm cannula to make the cannula compatible with 4.5 mm to 5.6 mm instruments.

- Reducer (model TR4-A12/8) is inserted into the 12 mm cannula to make the cannula compatible with 8 mm to 9.4 mm instruments.
- Reducer (model TR4-A15/8) is inserted into the 15 mm cannula to make the cannula compatible with 8 mm to 9.4 mm instruments.

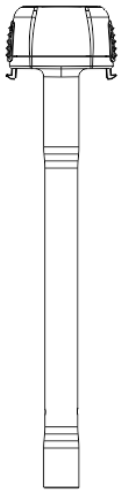


Figure 2.4 Reducer

2.2.2 Compatibility Information

The following table presents compatibility information of reducers, cannulas and cannula seals.

Reducer	Cannula	Cannula Seal
TR4-A8/5, Reducer	TR1-A8I, Cannula TR1-A8I-L, Long Cannula	TR3-A8, Cannula Seal
TR4-A12/8, Reducer	TR1-A12, Cannula TR1-A12-L, Long Cannula	TR3-A12, Cannula Seal
TR4-A15/8, Reducer	TR1-A15, Cannula TR1-A15-L, Long Cannula	TR3-A15, Cannula Seal

3. Inspection before Use

Before use, visually inspect the accessories for damage or defects.

Warning: Do not use the accessories with any defects or signs of damage. Otherwise, serious injury or surgical complications may occur to the patient.

3.1 Cannulas, Obturators and Cannula Seals

- Inspect cannulas and obturators for cleanliness. If there is residual soil on the device, clean and sterilize the device in accordance with the Accessories Reprocessing Instructions Manual.
- Inspect the integrity of cannulas, obturators and cannula seals. If any damage or abnormalities are observed, do not use the accessories.
- Hold the device up close and inspect for damage. Examples of damage include rough edges, dents, cracks, corrosions or a noncircular shape that may interfere with the smooth insertion of an instrument.

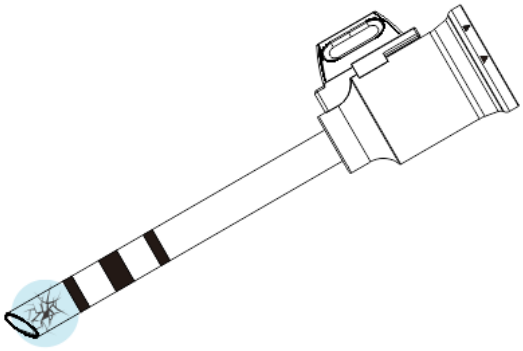


Figure 3.1 Examples of Cannula Defects

- Hold the cannula upright, drop the cannula accessory through the cannula with one hand and catch the cannula accessory with the other hand at the cannula tip. If the cannula accessory gets stuck, it indicates the cannula is damaged. There are 8 mm, 12 mm and 15 mm cannula accessories available for 8 mm, 12 mm and 15 mm cannula inspection.

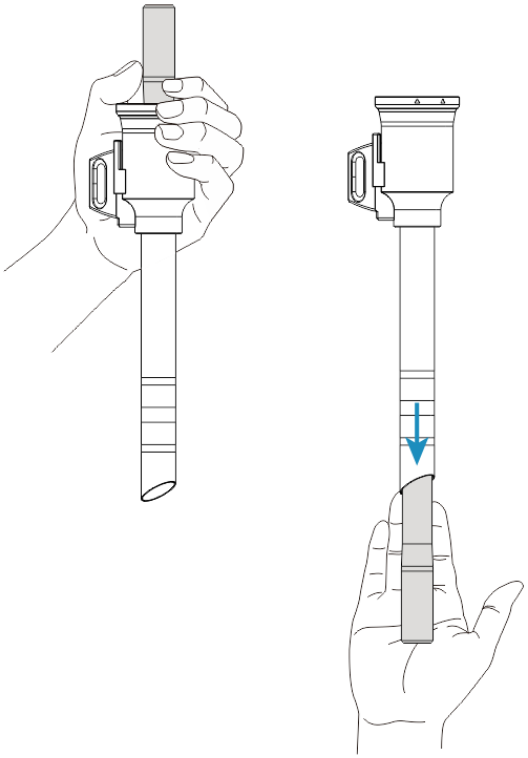


Figure 3.2 Use Cannula Accessory for Cannula Inspection

3.2 Reducers

- Reducers, is for single use only and comes in a sterile package. Inspect the packaging and ensure it has no tears. Do not use if the packaging is damaged or not intact.
- Confirm the date of manufacture and the shelf life and do not use any expired accessories.
- Inspect reducers for damage or abnormalities, for example, cracked or broken latches on the reducer cap.

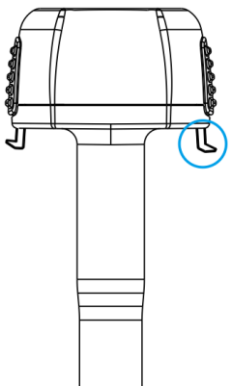


Figure 3.3 Examples of Reducer Defects

4. Intraoperative Operation

4.1 Cannulas, Obturators and Cannula Seals

Only a physician or medical personnel under the supervision of a physician should use accessories.

1. Inspect the accessories before use. See 3 Inspection before Use for details.
2. Using sterile technique, attach the compatible cannula seal to the cannula.

   Attach the cannula seal to the cannula by aligning the direction indicators as shown in Step ①and②, and then rotate the cannula seal until the direction indicators are aligned as shown in Step ③.

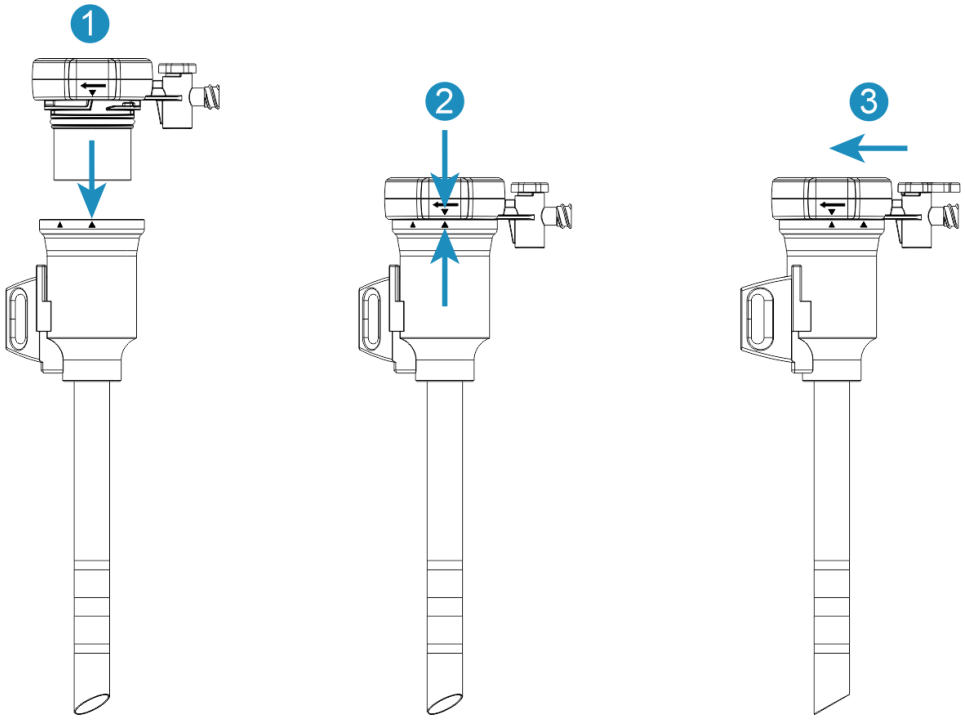


Figure 4.1 Cannula Seal and Cannula Assembly

3. Insert the obturator completely into the cannula seal and cannula until latched. Make sure it is fully engaged.

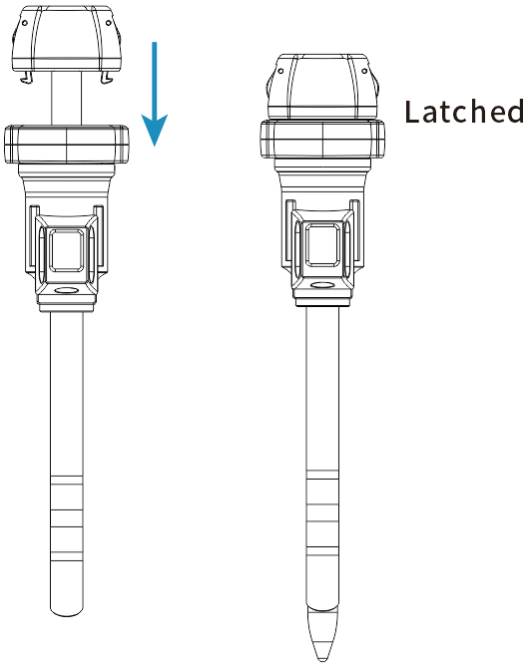


Figure 4.2 Obturator, Cannula Seal and Cannula Assembly

Warning: Follow the instructions to completely attach an obturator to a cannula and seal assembly. Failure to observe the instructions may result in incomplete attachment and unexpected detachment from the cannula.

4. Using standard surgical technique, make a skin incision to introduce the cannula and obturator. Note that the incision should match the cannula and obturator.
5. Hold the top of the cannula and obturator, and apply continuous, controlled pressure with a delicate rotating motion of approximately 180° until the cannula and obturator tip passes through the body wall.
6. When the cannula and obturator enter the body cavity, remove the obturator, leaving the cannula and cannula seal assembly in place.

Note: Do not remove the cannula seal to avoid unexpected loss of insufflation.

7. According to the specific procedure being performed, the remote center of the cannula marked in a thick black line should be placed within the boundaries of the body wall. If a patient has thicker body wall, use a long cannula.

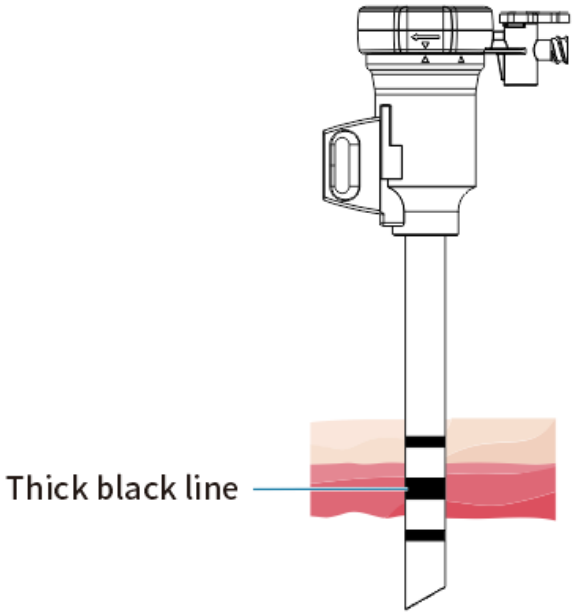


Figure 4.3 Remote Center Placement

8. Once all ports are placed, attaching cannulas to the Patient Cart arms by pressing and holding the cannula mount lever, inserting the cannula, and releasing the lever. Note that the insufflation port is not facing the arm.
9. Insert and remove the instrument and endoscope through the cannula and cannula seal intraoperatively. If a reducer needed to be inserted into a cannula to make the cannula compatible with an instrument, see 4.2 Reducers for details.
10. If the cannula seal is soiled intraoperatively, gently wipe with sterile gauze moistened with sterile saline or water as needed.
11. To remove the cannula, first detach the cannula and cannula seal assembly from the system, and then remove the cannula and cannula seal assembly from the body cavity.

4.2 Reducers

4.2.1 Attaching a Reducer

After removing the obturator, insert the reducer completely into the cannula seal and cannula until latched. Make sure it is fully engaged with an audible click.

Insert a compatible instrument through the reducer. See 2.2.2 Compatibility Information for details.

4.2.2 Removing a Reducer

To remove the reducer, firmly squeeze the reducer latches toward each other and then pull

the reducer out of the cannula and cannula seal assembly.

Note: Do not remove the cannula seal to avoid unexpected loss of insufflation.

5. Maintenance, Storage and Disposal

5.1 Maintenance

To maximize lifetime of cannulas and obturators, perform proper routine maintenance or service as follows:

- Place the accessories properly to avoid potential collisions with other objects and reduce the risk of contamination and damage.
- Handle with care to avoid mechanical shock or stress on the accessories.
- Regularly inspect lifetime of the accessories, and replace them once they run out of lifetime.
- Before and after each use, inspect the accessories for damage or abnormalities. Do not use if there is any visible damage or abnormality.
- Do not handle or maintain the accessories when in use.

5.2 Storage and Transport

- When transporting, make sure to place the accessories properly and handle with care. Protect the accessories from being cracked by heavy load, being scratched by hard objects, and being exposed to direct sunlight or water. Do not transport with volatile solvent or corrosive materials.
- Store the after-packing accessories in a clean, dry, well-ventilated room where there are no corrosive gases.

Storage and Transport Conditions	
Temperature	• Storage temperature: Room temperature • Transport temperature: -30℃～60℃
Relative humidity	5%～90%, non-condensing
Atmospheric pressure	700 hPa～1060 hPa

5.3 Disposal

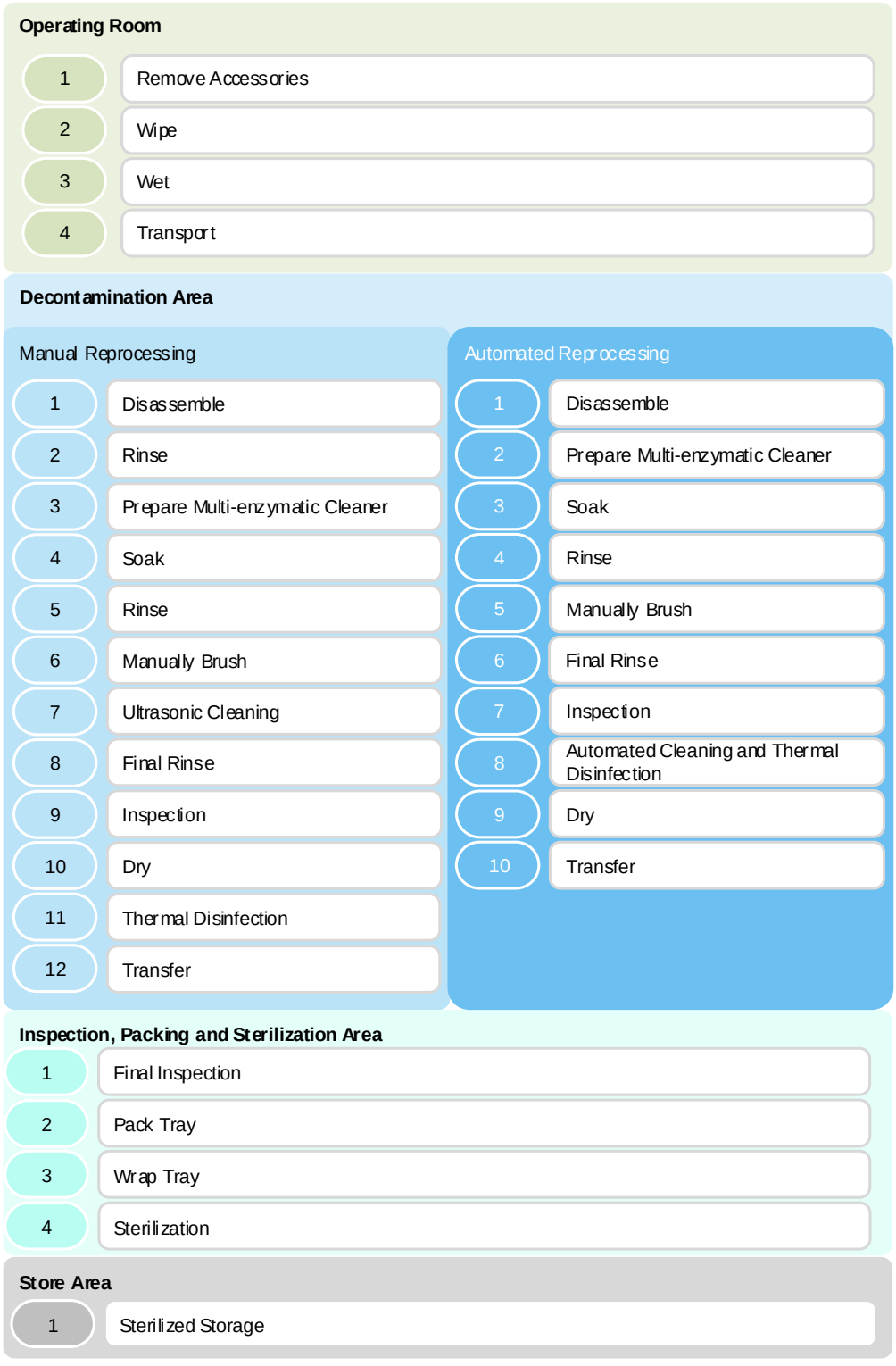
Cannulas and obturators are reusable accessories that cannot be used any more when they expire. Reducers and cannula seals, are intended for single use only. Discard the disposable accessories after each use and/or expiration, do not reuse or re-sterilize.

If the puncture kits need to be disposed, follow all applicable national and local laws and hospital practices. Contact your local Edge Medical representative for disposal information.

6. Reprocessing

For complete reprocessing information, refer to the Accessories Reprocessing Instructions Manual. Cannulas and obturators are shipped non-sterile and should be cleaned and sterilized thoroughly before first use and after every use.

6.1 Reprocessing Workflow



Note: The “Wet” step should begin within 60 minutes and it is recommended to begin reprocessing steps immediately after the procedure to avoid residual soil drying out on the instruments.

6.2 Sterilization Method and Parameter

Cannulas and obturators are sterilized by pre-vacuum steam sterilizer.

Validated Steam Sterilizer	
Manufacturer	**Model**
STERIS	AMSCO Century

Parameters	
Temperature and exposure time	132℃, for 4 minutes
	134℃, for 3 minutes
Dry time	30 minutes Based on the packing system, steam quality, load capacity of the sterilizer and environment conditions, the dry time may be different, 30 minutes recommended by the company. Dry time should be determined according to hospital policy.

Warning: Only sterilization machines, methods, parameters and cycles verified by the company can be used, and follow instructions in entirety. Unverified sterilization machines, sterilization methods (such as chemical sterilization), parameters (such as too high or too low sterilization temperature) or cycles may cause instruments damage or incomplete sterilization.

Caution: Following steam sterilization, allow all parts to cool to room temperature. Sudden changes in temperature may damage the parts.

Note: Dry time depends on the packing materials and load capacity of the sterilizer.

Note: The maximum sterilization time that has been validated for compatibility is 5 minutes. Follow any local regulations that may require a longer sterilization time.

Note: Please refer to sterilization system manufacturers' instructions for proper use of the system and recommendations for sterilization.

Appendix A Product Specifications

A.1 Cannulas

Product Name	Model	Min Inner Diameter		Working Length	
		Diameter	Tolerance	Diameter	Tolerance
Cannula	TR1-A8I	9.5 mm	±0.3 0	108.0 mm	±2%
Cannula	TR1-A8E	10.9 mm		108.0 mm	
Cannula	TR1-A12	14.4 mm		108.0 mm	
Cannula	TR1-A15	15.6 mm		108.0 mm	
Long Cannula	TR1-A8I-L	9.5 mm		158.0 mm	±2%
Long Cannula	TR1-A8E-L	10.9 mm		158.0 mm	
Long Cannula	TR1-A12-L	14.4 mm		158.0 mm	
Long Cannula	TR1-A15-L	15.6 mm		158.0 mm	

A.2 Obturators

Product Name	Model	Top Diameter		Working Length	
		Diameter	Tolerance	Diameter	Tolerance
Blunt Obturator	TR2-A8IB	9.4 mm	±0.3 0	192.0 mm	±2%
Blunt Obturator	TR2-A8EB	10.8 mm		194.0 mm	
Blunt Obturator	TR2-A12B	14.3 mm		199.0 mm	
Blunt Obturator	TR2-A15B	15.5 mm		201.0 mm	
Prismatic Obturator	TR2-A8IP	9.4 mm		192.0 mm	
Prismatic Obturator	TR2-A8EP	10.5 mm		194.0 mm	
Prismatic Obturator	TR2-A12P	14.3 mm		199.0 mm	
Prismatic Obturator	TR2-A15P	15.5 mm		201.0 mm	
Long Blunt Obturator	TR2-A8IB-L	9.4 mm		242.0 mm	
Long Blunt Obturator	TR2-A8EB-L	10.8 mm		244.0 mm	

Product Name	Model	Top Diameter		Working Length	
		Diameter	Tolerance	Diameter	Tolerance
Long Blunt Obturator	TR2-A12B-L	14.3 mm		249.0 mm	
Long Blunt Obturator	TR2-A15B-L	15.5 mm		251.0 mm	
Long Prismatic Obturator	TR2-A8IP-L	9.4 mm		242.0 mm	
Long Prismatic Obturator	TR2-A8EP-L	10.5 mm		244.0 mm	
Long Prismatic Obturator	TR2-A12P-L	14.3 mm		249.0 mm	
Long Prismatic Obturator	TR2-A15P-L	15.5 mm		251.0 mm	

A.3 Cannula Seals

Product Name	Model	Inner Diameter		Outer Diameter	
		Diameter	Tolerance	Diameter	Tolerance
Cannula Seal	TR3-A8	7.5 mm	±0.50	44.0 mm	±5.0%
Cannula Seal	TR3-A8E	7.5 mm		44.0 mm	
Cannula Seal	TR3-A12	10.0 mm		44.0 mm	
Cannula Seal	TR3-A15	10.0 mm		44.0 mm	

A.4 Reducers

Product Name	Model	Min Inner Diameter		Working Length	
		Diameter	Tolerance	Diameter	Tolerance
Reducer	TR4-A8/5	5.7 mm	±0.3 0	154.0 mm	±2%
Reducer	TR4-A12/8	9.5 mm		154.0 mm	
Reducer	TR4-A15/8	9.5 mm		154.0 mm	

Appendix B Intended Purpose Statements

Product Name	Model	Intended Purpose
Cannula	TR1-A8I	In combination with the endoscopic instrument control system, it is used to establish the working channel for endoscopic surgery.
	TR1-A8E	
	TR1-A12	
	TR1-A15	
Long Cannula	TR1-A8I-L	
	TR1-A8E-L	
	TR1-A12-L	
	TR1-A15-L	
Blunt Obturator	TR2-A8IB	In combination with the endoscopic instrument control system, the obturators are used to drill holes in the surface of the patient's skin during surgical procedures, preventing puncture or tearing of the body wall when the cannula is inserted into the patient.
	TR2-A8EB	
	TR2-A12B	
	TR2-A15B	
Prismatic Obturator	TR2-A8IP	
	TR2-A8EP	
	TR2-A12P	
	TR2-A15P	
Long Blunt Obturator	TR2-A8IB-L	
	TR2-A8EB-L	
	TR2-A12B-L	
	TR2-A15B-L	
Long Prismatic Obturator	TR2-A8IP-L	
	TR2-A8EP-L	
	TR2-A12P-L	
	TR2-A15P-L	

Product Name	Model	Intended Purpose
Cannula Seal	TR3-A8	In combination with the endoscopic instrument control system, it is used to ensure that cannula is not leakage when the surgical instrument is inserted and to enhance the sealing of the cannula.
	TR3-A8E	
	TR3-A12	
	TR3-A15	
Reducer	TR4-A8/5	In combination with the endoscopic instrument control system, it is used to transfer surgical instruments.
	TR4-A12/8	
	TR4-A15/8	

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