[ENDO REACH FLEXA Trocars]
EN **Trocars for Single Use** Instructions

CE 0197

	Reach Surgical. Inc. 120 Xinxing Road,West Zone,TEDA,300462 Tianjin,China
EC REP	**MDSS GmbH** Schiffgraben 41,30175 Hannover,Germany

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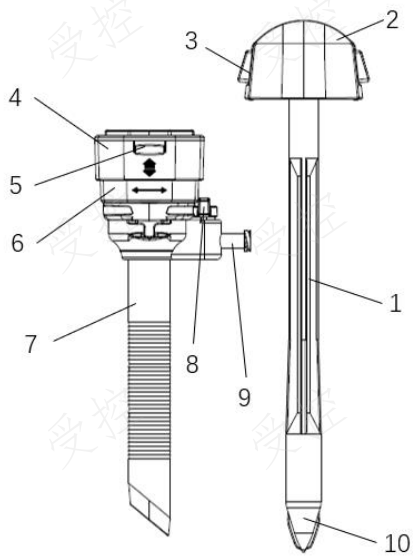
Illustrations



EN/English

Before using the instrument, please read the following contents carefully.
This document is designed to assist in using this instrument. It is not a reference for surgical techniques.
This instrument is designed, inspected, and manufactured for single use only. Do not reuse, reprocess or resterilize this instrument. Reusing or reprocessing may result in instrument failure or patient injury.

Standard Conventions Used: Caution, Warning, and Note Statements

Information relative to the completion of a task in a safe and thorough manner will be supplied in the form of a Caution, WARNING, or Note statement. These statements are found throughout the documentation. These statements should be read before continuing to the next step in a procedure.
Warning: A Warning statement indicates an operating or maintenance procedure, practice, or condition that, if not strictly observed, could result in personal injury or loss of life.

Caution: A Caution statement alerts the user of a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient or damage to the equipment or other property. It may also be used to alert against unsafe practices. This includes the special care necessary for the safe and effective use of the instrument and the care necessary to avoid damage to the instrument that may occur because of use or misuse.

Note: A Note statement indicates an operating, practice, or condition that is necessary to execute a task efficiently.

Description

The Trocars for Single Use (Hereinafter referred to as 'the instrument') is a sterile single patient use instrument consisting of a cannula and obturator in sizes 5mm, 11mm, 12mm and 15mm diameter. The cannulas for 5mm,11mm,12mm,15mm model contain two seals, an outer integrated removable seal that accommodates devices ranging from 5 mm to 15 mm in diameter and a removable internal seal. Together, these two seals minimize gas leakage when devices are inserted or withdrawn through the instrument. A stopcock valve is compatible with standard luer lock fittings and provides attachment for gas insufflation and desufflation. The stopcock is in the closed position when it is parallel to the cannula.

Nomenclature – Instrument (Illustration 01)

1	Obturator
2	Obturator Handle
3	Obturator Locking Button
4	Adapter Cap
5	Adapter Cap Release Lever
6	Secondary Seal Housing
7	Cannula
8	Stopcock Lever
9	Stopcock
10	Obturator Tip

Product Specifications

Chart 01 - Product codes and specifications

Code	Diameter of Cannula	Working Length of Cannula	Suitable Device Diameter	Configuration
SM5SL	5mm	70 mm	5mm	Cannula +Obturator

SM5DL	5mm	100mm	5 mm	Cannula +Obturator
SM5XL	5mm	150mm	5 mm	Cannula +Obturator
SM11DL	11 mm	102mm	5-11 mm	Cannula +Obturator
SM12DL	12 mm	102mm	5-12 mm	Cannula +Obturator
SM12XL	12mm	152mm	5-12 mm	Cannula +Obturator
SM15DL	15mm	118mm	5-15 mm	Cannula +Obturator
SM15XL	15mm	168mm	5-15 mm	Cannula +Obturator
SME5SL	5mm	70 mm	5mm	Two Cannulas +Obturator
SME5DL	5mm	100mm	5 mm	Two Cannulas +Obturator
SME12DL	12mm	102mm	5-12 mm	Two Cannulas +Obturator
S5DL	5 mm	100mm	5 mm	Only Cannula
S12DL	12mm	102mm	5-12 mm	Only Cannula

The instrument is intended to be used as a port for devices. The devices' maximum insertion portion diameter should be less than the cannula's inner diameter specified, and the sheath length shall be longer than the total length of the cannula. With appropriate adapter cap the seal is ensured, smaller diameter devices are compatible.
The instrument is capable of being used associated with insufflator. The insufflator shall provide standard lure lock fittings for stopcock.

Intended Use and Indications

This instrument has applications in abdominal, thoracic and gynecologic minimally invasive surgical procedures to establish a path of entry for endoscopic devices.

Intended User

This instrument is used for healthcare professionals who use this instrument for surgical purposes.

Intended Use Environment

This instrument is intended to be used in a hospital.

Intended patient population and medical condition to be treated

For laparoscopic surgery and micro-incision surgery patients over 3 years old.

Clinical Benefits

This instrument can be used safely and effectively to establish a path of entry for endoscopic devices.

Contraindications

- This instrument is not intended to be used on neonatal patients; use on pregnant women should be

made with caution.

- This instrument is not intended for use when minimally invasive techniques are contraindicated.

Instructions for Use

Before use, inspect the package of all sterile components to ensure that the integrity has not been compromised. Verify compatibility of all devices and accessories prior to using the instrument.
Note: The cannula and obturator should be used in conjunction for insertion.

1. Using sterile technique, remove the instrument from the package. To avoid damage, do not fip the instrument into the sterile field.
2. The obturator and cannula are packaged unassembled. To assemble, remove the protective tip covering from the obturator and cannula and discard. Assemble the instrument by inserting the obturator into the cannula until they lock securely together.
   Note: The instrument is packaged with the stopcock in the open position. Close the stopcock before use. The stopcock is closed when the stopcock lever is parallel to the cannula.
3. Create an incision using standard surgical procedure which allows the instrument to be introduced.
   Note: An inadequate incision may cause increased resistance to insertion, increasing the required penetration force, and possibly resulting in a loss of control during entry. An incision too large may increase the potential for port instability.
   Warning: The failure to make an adequate incision, the application of excessive force or incorrect insertion may increase the risk of injury to internal structures.
4. Establish pneumoperitoneum prior to introduction, refer to the standard pneumoperitoneum procedure of the pneumoperitoneum device, e.g. Veress Needle.
5. Introduce the instrument assembly through the abdominal wall at the appropriate angle to the abdomen by applying a continuous downward force to the instrument while gently rotating in alternating clockwise and counterclockwise directions until the obturator tip enters the abdominal cavity.
6. When the instrument is in the abdominal, press the obturator locking buttons to remove the obturator, leaving the cannula in place. The internal seal in the cannula automatically closes as the obturator is withdrawn. The seal system maintains insufflation in the absence of a device in the cannula.
7. Establish pneumoperitoneum after insertion (If not established prior). Connect the insufflation tubing to the stopcock on the cannula and turn on the stopcock lever. Turn on the insufflator at the desired settings. Recommended pressure is less than 4KPa.
8. Once the abdominal cavity is sufficiently distended, complete the insertion by applying continuous downward force to the instrument while gently rotating in alternating clockwise and counterclockwise

directions, until placed as desired.

Appropriately sized endoscopic devices may now be inserted and removed through the cannula.

9. For specimen removal during the procedure, the seal can be partially or fully removed from the cannula, de-sufflation or per physician need.

- Detach Semi-Detachable Seal

To partially remove the seal, simultaneously squeeze the tabs above the symbol  on both sides of the adapter cap, then pull up the Adapter Cap.

- Detach Fully-Detachable Seal

To fully remove the seal, twist the seal assembly with the following symbol .

Caution: When the seal is fully removed, the de-sufflation will immediately engage. Use with caution.

10. Upon completion of the remove the gas line. Open the stopcock to rapidly deflate the abdominal cavity.
11. Remove the cannula from the operative site. Use continuous upward force while gently rotating the cannula in alternating clockwise and counterclockwise directions until the cannula is completely removed.

Disposal

Dispose this instrument according to local law. This instrument is safe for disposal as no sharp edges/needle exposed.

Warnings and Precautions

- Do not use if the package is opened or damaged. It may cause cross-infection if used.
- Failure to establish and maintain appropriate pneumoperitoneum in abdominal procedures may reduce available free space, increasing the risk of injury to internal structures.
- Endoscopic procedures should be performed only by physicians having adequate medical training and familiarity with endoscopic techniques. Medical literature relative to techniques, complications and hazards should be consulted prior to use.
- This instrument in contact with bodily fluids and require special disposal handling as infectious waste to prevent biological contamination.
- This instrument is packaged and sterilized for single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing, or re-sterilization may compromise the structural integrity of the instrument and/or lead to failure that in turn may result in patient injury, illness or death. Also, reprocessing or

resterilization of single use instruments may create a risk of contamination and/or cause patient infection or cross infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another.

- An insufficient skin incision may cause increased penetration force which may reduce the surgeon's control during entry. An incision too large may increase the potential for port instability. Additional stability devices such as suturing to the Tie Down may be required.
- Before and after removal of the instrument from the abdominal, inspect the site for hemostasis. Bleeding may be controlled by electrocautery or manual sutures.
- Before endoscopic devices and accessories from different manufacturers are used, verify compatibility and ensure that electrical isolation or grounding is not compromised. The manufacture's size designation number may not represent the actual size.
- When using this instrument with energy based devices, a thorough understanding of the principles and techniques involved in laser and electrosurgical laparoscopy procedures is essential to avoid shock and burn hazards to both patient and operator(s), and damage to the instrument.
- Closure of the fascia is at the discretion of the surgeon. Underlying fascia may be closed, e.g., by suturing to reduce the potential for incisional hernias.
- Use caution when introducing or removing devices through the cannula in order to prevent inadvertent damage to the seals which could result in loss of pneumoperitoneum. Special care should be used when inserting sharp or angled edged endoscopic devices to prevent tearing the seal.
- In abdominal procedures, the incorrect perpendicular instrument insertion could result in an aortic puncture. The correct insertion is at an angle with the patient in the Trendelenburg position.
- Once complete entry has been made into the abdominal, the instrument should not be advanced for additional penetration. Continued entry of the obturator at this point could cause injury to intra-abdominal structures.
- Once partial entry has been accomplished, very little pressure may be required to complete entry. Excessive pressure could cause injury to intra-abdominal structures.
- Maintain space between distal anatomy and the obturator tip during insertion and desufflation to

minimize risk of trauma.

- Using devices with a diameter smaller than suitable diameter specified for the instrument may result in loss of pneumoperitoneum.
- When the seal is fully removed, the de-sufflation will immediately engage. Use with caution.
- Dispose of all opened instruments whether used or unused.
- A notice to the user and/or patient that any serious incident that has occurred in relation to the instrument should be reported to Reach Surgical, Inc. through Reachquality@reachsurgical.com and the competent authority of the Member State in which the user and/or patient is established.

Technical Parameters

- The instrument stopcock lever can open and close flexibly.
- The instrument cannula and obturator fit well, insert and remove smoothly.
- The instrument filling valve and sealing cap should be no leakage under the pressure of 4Kpa.

Storage Requirements

Storage at room temperature, keep away from chemical fumes. Humidity less than 80%.

Transport Requirements

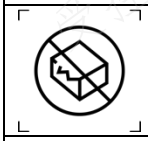
Temperature: -10℃～54℃
Relative Humidity: ≤80%

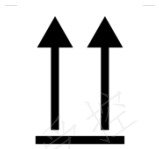
Expiration Date

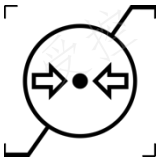
The instrument is sterilized by Ethylene Oxide. The expiration date is labeled on the package. Do not use if this instrument beyond its expiration date.

How Supplied

This instrument is supplied sterile for single patient use. Discard after use.

	Sterilization batch
	Peel Here
	HDPE recyclable
	Recyclable
	Authorized Representative in the European Community
	Do not use if package is damaged.
	Do not resterilize
	Manufacturer
	Date of manufacture
	Serial number
	Batch code

	Use-by date
	Fragile, handle with care
	Keep dry
	Keep away from sunlight
	Up
	Do not re-use
	Caution
	Catalogue number
	Storage temperature limit
	Storage humidity limitation

	Storage atmospheric pressure limitation
	Single sterile barrier system with protective packaging inside
	Country of manufacture
	Medical device
	Unique device identifier
	Sterilized by Ethylene Oxide.
	Consult instructions for use or consult electronic instructions for use