EZCATCH®

(Auto Variant)

Tissue Retrieval Bag

INSTRUCTIONS FOR USE



REFER TO INSTRUCTION MANUAL/ BOOKLET

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CAUTION: Device to be sold on the order of a licensed physician.

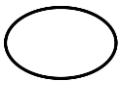
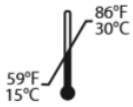
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Symbols

Table 1: Meaning of symbols used in this IFU and on the product.

	**Sterilized using ethylene oxide**
	**Consult Instruction for Use**
	**Do not use if pack is open or damaged**
	**Do not re-use**
	**Do not re-sterilize**
	**Date of manufacture**
	**Manufacturer** Veol Medical Technologies Pvt. Ltd. A-747, Near Pavan Bus Stop, MIDC Pawane, TTC Industrial Area, Navi Mumbai 400705. Maharashtra, India. Ph: +91-882-882-0407 Email: info@veolmedtech.com Website: www.veolmedtech.com
	**Medical Device**
	**Keep away from direct sunlight**
	**Keep dry**
	**Caution** See instruction for use

	**Single sterile barrier system**
	**Expiry date**
	**Latex Information:** The EzCatch Tissue Retrieval Bag is latex free.
	**To be sold on prescription only**
	**Store at room temperature**

Date of Initial Issue: 02-07-2021
Date of Revision: 01-10-2025

EzCatch (Auto Variant) Tissue Retrieval Bag

INSTRUCTIONS FOR USE

Please read all information carefully

Before using the product, please read all information provided in this booklet carefully

This Instruction for Use (IFU) manual is intended to act as technical guideline and not as a training manual. The physician should read this entire manual with particular attention to the **Warnings and Precautions** and be thoroughly familiar with the use of the device prior to performing any clinical procedure. It is not a reference to surgical techniques.

1. GENERAL INFORMATION

The following Instructions for Use are intended for the use of EzCatch Auto Variant.

2. DEVICE DESCRIPTION

The EzCatch Tissue Retrieval Bag consists of a long cylindrical tube (Deployer Handpiece/ Introducer) and a polyurethane bag (Tissue Retrieval Bag) that minimizes spillage and intraoperative contamination by isolating and containing specimens. This device is designed for introduction and use through all appropriately sized trocar sleeve (of generally 10mm size).

This IFU provides the details of **Auto variant** of EzCatch Tissue Retrieval Bag- **EzCatch (Auto).** Please refer IFU no (TRB-L-0202) for the **Manual variants (TR & YR)** of EzCatch Tissue Retrieval Bag.

2.1 Intended Use

The EzCatch (Auto) Tissue Retrieval Bag is intended for containment and removal of tissues during laparoscopic surgeries.

2.2 Indications

The EzCatch Tissue Retrieval Bag has application for safe, convenient removal of tissue specimens such as the appendix, an ectopic pregnancy, gallbladder, gallstones, lymph nodes, ovaries, small sections of bowel and other tissue structures.

2.3 Intended patient population

The EzCatch (Auto) is intended to be used in patients aged 18 years and older and indicated for all laparoscopic procedures. The patient should have appropriate medical status to undergo surgery. The indications for surgery may vary from patient to patient.

2.4 Intended user profile

The device is intended to be handled by medical professionals qualified in the preparation, manipulation and use of surgical devices. This includes surgeons, scrub technicians, circulating nurses and qualified medical staff.

2.5 Contraindications

2.5.1 This device is not intended for use except as indicated. DISCARD AFTER USE. DO NOT RESTERILIZE OR REPROCESS.

2.5.2 This device is not intended for removal of tissue that does not fit in the bag or comparatively bigger in size.

2.5.3 The removal of device to be done as instructed in the standard procedure. DO NOT REMOVE THE SPECIMEN BAG THROUGH OUTER TUBE OF EzCatch DEVICE OR TROCAR SLEEVE.

2.5.4 This device not to be used in conjunction with morcellators.

3. WARNING AND PRECAUTIONS

3.1 Laparoscopic procedures should be performed only by physicians having adequate training and familiarity with laparoscopic techniques. Consult the medical literature relative to techniques, complications and hazards prior to performance of any laparoscopic procedure.

3.2 Before laparoscopic instruments and accessories from different manufacturers are employed together in a procedure, verify compatibility and ensure that electrical isolation or grounding is not compromised.

3.3 A thorough understanding of the principles and techniques involved in laser laparoscopy and electrical procedure is essential to avoid shock and burn hazards to both patient and operator(s), and damage to the instrument.

3.4 Do not open the flexible metal spring until the tip of the instrument outer tube has cleared the trocar sheath

3.5 Metal spring should be retracted completely into the Device/Outer tube prior to removal through trocar sleeve.

3.6 Do not pull the specimen bag through trocar sleeve or outer tube of the instrument. The bag can be removed through a 10mm trocar site, if bag does not pull through easily, enlarge the incision to accommodate easy removal for specimens with diameters larger than the trocar site incision, taking care not to puncture the bag. Failure to follow this warning could cause the bag to break and the specimen to fall back into the body cavity.

3.7 While using EzCatch bag in conjunction with exposed blades or cutting instruments, care should be taken to avoid contact with EzCatch device as this may rupture the bag.

3.8 EzCatch is sterile device and intended for use in a single procedure only.

3.9 Instruments or devices which come into contact with bodily fluids may require special disposal handling to prevent biological contamination.

3.10 Always check the sterile packaging for any damage before use. If damaged, the product should not be used.

3.11 Device to be used with Trocar size of 10mm.

3.12 Voluntarily open the Trocar flap whenever required while inserting the device through trocar.

3.13 Care should be taken to avoid contact of the bag with sharp instruments, cutting devices, electrocautery and laser or other instruments.

3.14 This device is packaged and sterilized for single use only. Do not reuse, reprocess or re-sterilize. Reuse, reprocessing, or re-sterilization may compromise the structural integrity of the device and/or lead to device failure that in turn may result in patient injury, illness or death. Also, reprocessing or re-sterilization of single use devices may create a risk of contamination and/or cause patient infection or cross infection, including, but no limited to the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

4. ADVERSE REACTIONS

Bag ruptures may result in spillage of fluid or tissue specimens.

5. TECHNICAL SPECIFICATIONS

EzCatch (Auto) is available and supplied in a single Small (S), Medium (M), Large (L) and Extra Large (XL) size version. The detailed specification of available version is as follows:

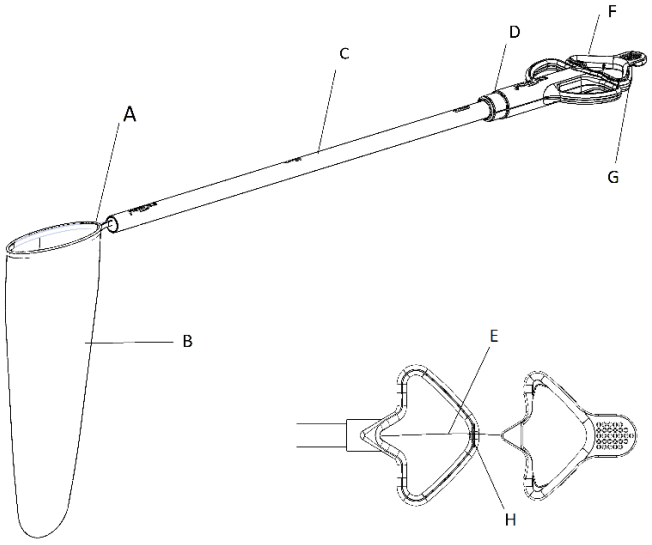
5.1 Technical Specification for Tissue Retrieval Bag:

Sr. No.	Size	Bag Opening Width	Bag Opening Diameter	Bag height	Volume (Working Space)
1.	Small (S)	75 mm	≈ 45mm	175mm	150 ml
2.	Medium (M)	100 mm	≈ 60mm	160mm	250 ml
3.	Large (L)	125 mm	≈ 75mm	180mm	400 ml
4.	Extra Large (XL)	140 mm	≈ 85mm	210mm	700 ml

5.2 Technical Specification for Deployer Handpiece/Introducer:

Sr. No.	Description	Size
1.	Deployer Handle (S, M, L, XL)	10mm [Diameter]

6. SCHEMATIC VIEW



A - Flexible Metal Spring
B - Retrieval Bag
C - Outer Tube
D - Deployer Handle
E - Thread
F - Suture tab
G - Pusher
H - Cutting blade

Figure No. 1 - EzCatch (Auto) Tissue Retrieval Bag

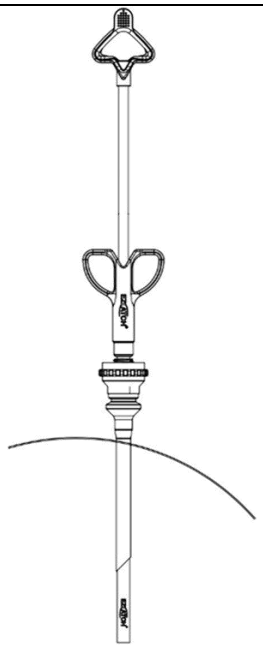
7. PROCEDURAL STEPS

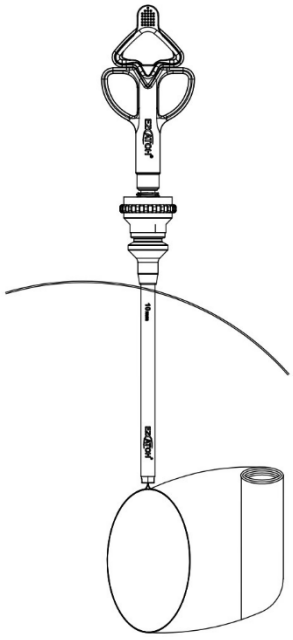
7.1 Section No. 1: Capturing Tissue into EzCatch bag

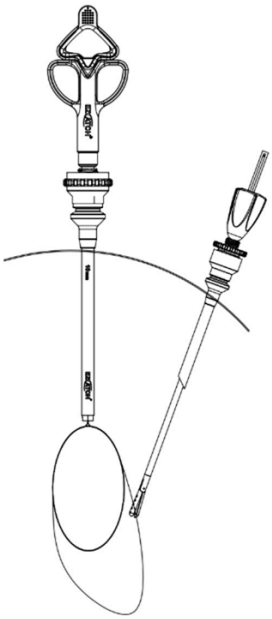
7.1.1 To remove a disposable EzCatch Tissue Retrieval Bag from its sterile package, peel chevron seal of the Tyvek pouch and proceed with instructions below.
7.1.2 Remove the safety lock from device.
7.1.3 Insert the instrument through a trocar sleeve (10mm). Ensure that the “THIS SIDE UP” printing (available on pusher) is facing up, indicating that the mouth of the bag will be in the proper position for specimen retrieval. (Refer figure no. 2).
7.1.4 Ensure tip of deployer/outer tube has cleared the trocar sheath. In a syringe like fashion push the pusher forward so that the bag is advanced into the cavity. The mouth of the bag is maintained in an open position without the aid of additional instruments, by a flexible metal spring. Ensure that the pusher is completely pushed forward before proceeding further. (Refer figure no. 3)
7.1.5 The bag can be unrolled using an atraumatic instrument i.e. surgical grasper etc. (Refer figure no. 4)
7.1.6 Place specimen into the bag. Once the specimen is completely within the bag (See figure no. 5), detach the suture tab and leave it hanging away from the pusher as shown below (Refer figure no. 6).
7.1.7 Ensure that the cutting blade is facing up prior to detaching the suture tab from the pusher. (Refer figure no. 7)
7.1.8 Leaving the suture tab with thread aside, pull the pusher handle so that the metal spring from the bag is retracted into outer tube. (Refer figure no. 8)

Note: Flexible metal spring is divided into two haft to avoid the tearing of bag.
Important: Leave space between the specimen bag and the tip of the outer tube.

Please Refer the below procedural figures for feasible operation.


Figure No. 2


Figure No. 3


Figure No. 4

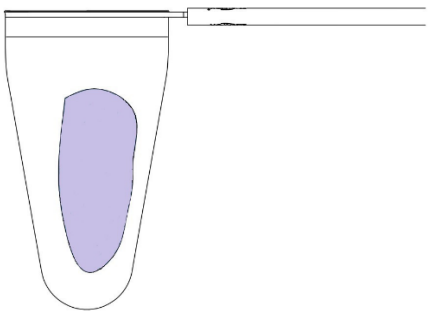


Figure No.5

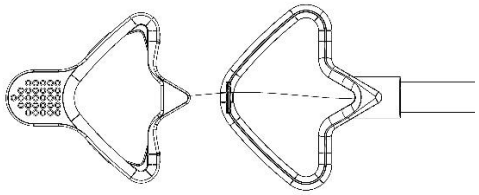


Figure No. 6

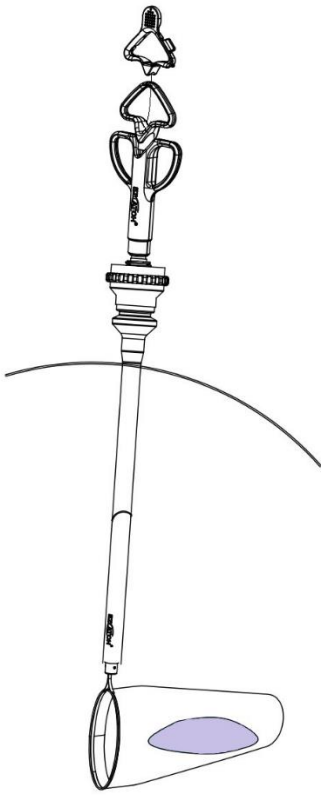


Figure No. 7

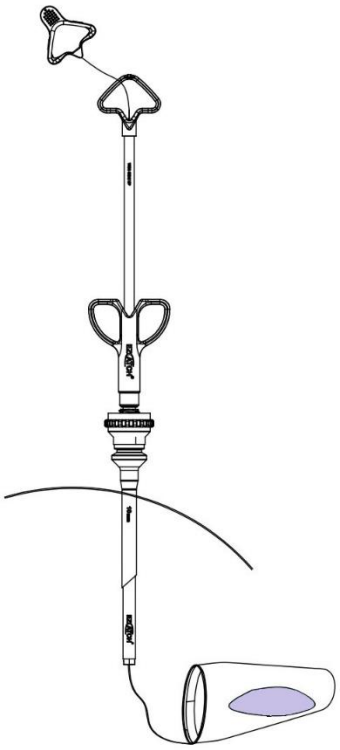


Figure No. 8

7.2 Section No.2: Removing the instrument, specimen bag and trocar

7.2.1 Once the spring is completely retracted, pull the suture tab along with the thread till the mouth of the bag is closed. (Refer figure no. 9)

7.2.2 In this condition take the thread against the blade provided on the pusher and cut off the thread. This separates the bag from the deployer handle (remaining body). (Refer figure no.10)

7.2.3 Now, leaving the bag inside the patient's body, pull out the deployer handle and the trocar leaving just the bag with thread inside the body. The end of the thread should come out of the incision in the body. (See figure no.11)

7.2.4 Using the end of the thread (tip of the separated thread), pull out the specimen bag from the incision (See figure no. 12)

7.2.5 If there is air trapped inside the bag, slightly open the mouth of the bag with a grasper and allow the air to escape and then pull the bag out. If bag does not pull through easily, enlarge the incision or manually dissect the tissue into smaller pieces inside the bag to accommodate easy removal of bag, while doing so take care not to puncture or damage the bag or cut the thread.

7.2.6 EzCatch bag is not intended for removal of large volume of insufficiently dissected tissue from the abdomen cavity unless the abdominal incision is accordingly enlarged for its removal. Excessive attempts to pull such tissue through a small incision could lead to damage to EzCatch bag with resulting spillage of tissue into the peritoneal cavity.

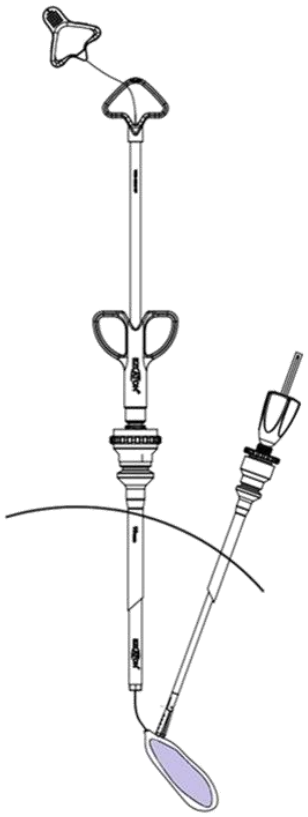


Figure No. 9

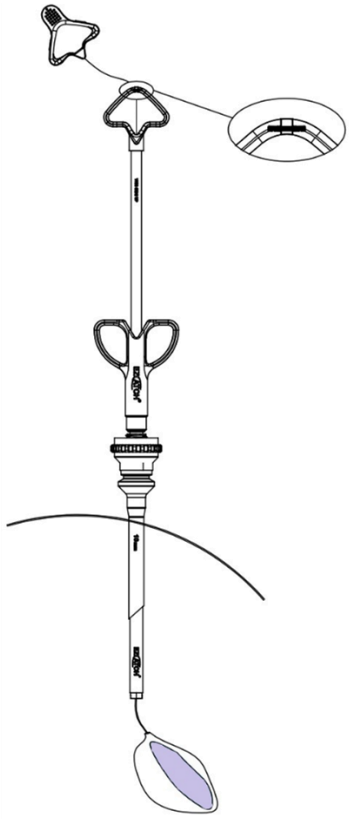


Figure No. 10

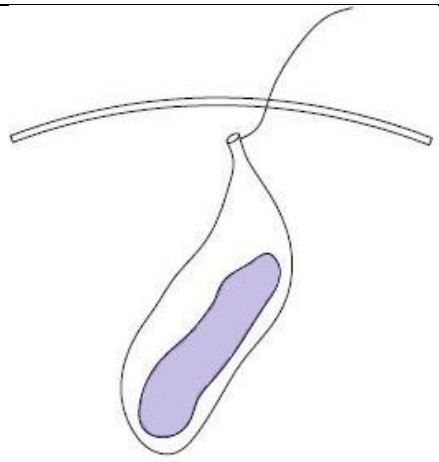


Figure No. 11

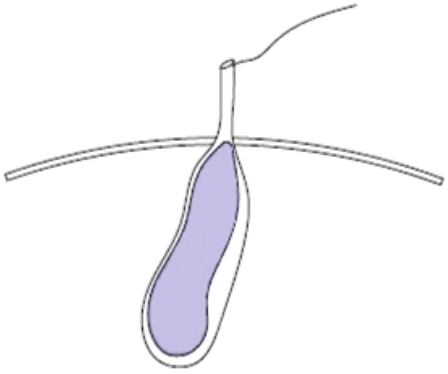


Figure No.12

8. HOW SUPPLIED

The EzCatch (Auto) Tissue Retrieval Bag is packaged in peel-open Tyvek™ pouches. The product is supplied sterile and is intended for one-time use.
Do not use if the packaging of the product is damaged or opened. Store EzCatch in a dry and cool place. Avoid extended exposure to light. Upon removal from package in an aseptic or sterile area, inspect the product to ensure no damage has occurred.

9. TRANSPORT, STORAGE AND CARE CONDITIONS

Transport and Store EzCatch (Auto) Tissue Retrieval Bag in a clean and dry area away from the direct sunlight.

- Storage: (+15°C to +30°C) & (59°F to 86°F)
- Transportation: -10°C to + 60°C.

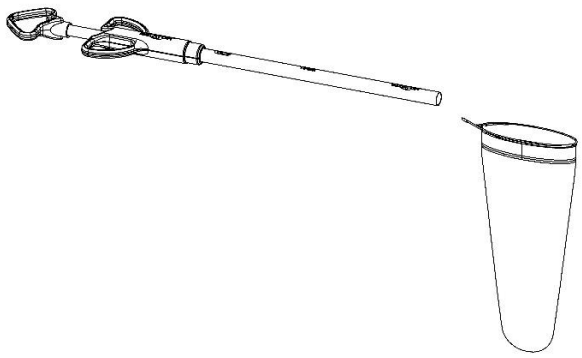
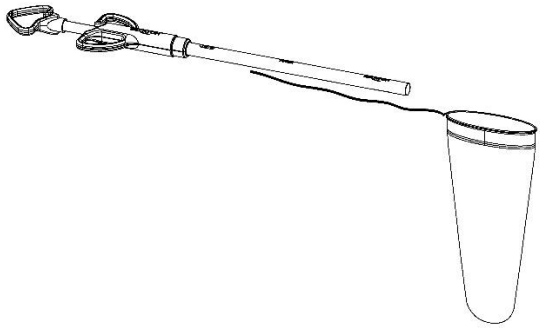
After use, dispose EzCatch and its packaging in accordance with hospital, administrative and/or local government policy.

EzCatch (Auto) Tissue Retrieval Bag is packaged as a STERILE device. EzCatch (Auto) Tissue Retrieval Bag is intended for one-time surgical use only. Do not reprocess, re-use or re-sterilize EzCatch (Auto) Tissue Retrieval Bag.

Caution:

- Avoid prolonged exposure to elevated temperatures.
- Do not attempt to pull bag through trocar or outer tube of the instrument.
- Do not attempt to pull specimen bag through trocar sleeve.
- Federal law restricts this device to sale by or on the order of a physician

(YR & TR Variant)
Tissue Retrieval Bag
INSTRUCTIONS FOR USE

	
EzCatch YR S | M | L | XL	**EzCatch TR** S | M | L | XL

REFER TO INSTRUCTION MANUAL/ BOOKLET

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CAUTION: Device to be sold on the order of a licensed physician.

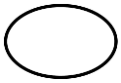
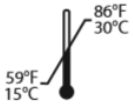
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Symbols

Table 1: Meaning of symbols used in this IFU and on the product.

	**Sterilized using ethylene oxide**
	**Consult Instruction for Use**
	**Do not use if pack is open or damaged**
	**Do not re-use**
	**Do not re-sterilize**
	**Date of manufacture**
	**Manufacturer** Veol Medical Technologies Pvt. Ltd. A-747, Near Pavan Bus Stop, MIDC Pawane, TTC Industrial Area, Navi Mumbai 400705. Maharashtra, India. Ph: +91-882-882-0407 Email: info@veolmedtech.com Website: www.veolmedtech.com
	**Medical Device**
	**Keep away from direct sunlight**
	**Keep dry**
	**Caution** See instruction for use

	**Single sterile barrier system**
	**Expiry date**
	**Latex Information:** The EzCatch Tissue Retrieval Bag is latex free.
	**To be sold on prescription only**
	**Store at room temperature**

Date of Initial Issue: 05-04-2021
Date of Revision: 01-10-2025

EzCatch (YR & TR Variant) Tissue Retrieval Bag

INSTRUCTION FOR USE

Please read all information carefully

Before using the product, please read all information provided in this booklet carefully.

This Instruction for Use (IFU) manual is intended to act as technical guideline and not as a training manual. The physician should read this entire manual with particular attention to the **Warnings and Precautions** and be thoroughly familiar with the use of the device prior to performing any clinical procedure. It is not a reference to surgical techniques.

1.0 GENERAL INFORMATION

The following Instructions for Use are intended for the use of EzCatch YR & TR Variants.

2.0 DEVICE DESCRIPTION

The EzCatch Tissue Retrieval Bag consists of a long cylindrical tube (Deployer Handpiece/ Introducer) and a polyurethane bag (Tissue Retrieval Bag) that minimizes spillage and intraoperative contamination by isolating and containing specimens. This device is designed for introduction and use through trocar sleeve of 10mm.

This IFU provides the details of **TR & YR variant** of EzCatch Tissue Retrieval Bag – **EzCatch (TR & YR)**. Please refer IFU no (TRB-L-0201) for the **Auto variant** of EzCatch **(Auto)** Tissue Retrieval Bag.

- **EzCatch (TR):** This variant has a thread at the opening of Tissue Retrieval Bag.
- **EzCatch (YR):** This variant has a nitinol wire at the opening of Tissue Retrieval Bag.

2.1 Intended Use

The EzCatch (TR & YR) Tissue Retrieval Bag is intended for containment and removal of tissues during laparoscopic surgeries.

2.2 Indications

The EzCatch tissue retrieval bag has application for safe convenient removal of tissue specimens such as the appendix, an ectopic pregnancy, gallbladder, gallstones, lymph nodes, ovaries, small sections of bowel and other tissue structures.

2.3 Intended patient population

The EzCatch (YR & TR) is intended to be used in patients aged 18 years and older and indicated for all laparoscopic procedures. The patient should have appropriate medical status to undergo surgery. The indications for surgery may vary from patient to patient.

2.4 Intended user profile

The device is intended to be handled by medical professionals qualified in the preparation, manipulation and use of surgical devices. This includes surgeons, scrub technicians, circulating nurses and qualified medical staff.

2.5 Contraindications

2.5.1 This device is not intended for use except as indicated. DISCARD AFTER USE. DO NOT RESTERILIZE OR REPROCESS.
2.5.2 This device is not intended for removal of tissue that does not fit in the bag or comparatively bigger in size.
2.5.3 The removal of device to be done as instructed in the standard procedure. DO NOT REMOVE THE SPECIMEN BAG THROUGH OUTER TUBE OF EzCatch DEVICE OR TROCAR SLEEVE.
2.5.4 This device not to be used in conjunction with morcellators**.**

3.0 WARNING AND PRECAUTIONS

3.1. Laparoscopic procedures should be performed only by physicians having adequate training and familiarity with laparoscopic techniques. Consult the medical literature relative to techniques, complications and hazards prior to performance of any laparoscopic procedure.
3.2. Before laparoscopic instruments and accessories from different manufacturers are employed together in a procedure, verify compatibility ensure that electrical isolation or grounding is not compromised.
3.3. A thorough understanding of the principles and techniques involved in laser laparoscopy and electrical procedure is essential to avoid shock and burn hazards to both patient and operator(s), and damage to the instrument.
3.4. Do not pull the specimen bag through trocar sleeve or deployer handle of the instrument. The bag can be removed through a 10mm trocar site. If bag does not pull through easily, enlarge the incision to accommodate easy removal for specimens with diameters larger than the trocar site incision, taking care not to puncture the bag. Failure to follow this warning could cause the bag to break and the specimen to fall back into the body cavity.
3.5. EzCatch is sterile device and intended for use in a single procedure only.
3.6. Instruments or devices which come into contact with bodily fluids may require special disposal handling to prevent biological contamination.
3.7. Always check the sterile packaging for any damage before use. If damaged, the product should not be used.
3.8. Device to be used with Trocar size of 10mm.
3.9. Voluntarily open the Trocar flap whenever required while inserting the device through trocar.
3.10. Care should be taken to avoid contact of the bag with sharp instruments, cutting devices, electrocautery and laser or other instruments.
3.11. Oxidized Nitinol wire, which is an alloy of Nickel and Titanium, is used in the construction of EzCatch (YR) variant, therefore, do not use this device in patients with sensitivity to Nickel.

4.0 ADVERSE REACTIONS

Bag ruptures may result in spillage of fluid or tissue specimens.

5.0 TECHNICAL SPECIFICATIONS

EzCatch (TR & YR) variants are available and supplied in Four different versions i.e. Small (S), Medium (M), Large (L) and Extra Large (XL). The detailed specification of available versions are as follows:

5.1 Technical Specification for Tissue Retrieval Bag

Sr. No.	Size	Bag Opening Width	Bag Opening Diameter	Bag Height	Volume (Working Space)
1.	Small (S)	75mm	≈ 45 mm	175mm	150ml

2.	Medium (M)	100mm	≈ 60 mm	160mm	250ml
3.	Large (L)	125mm	≈ 75 mm	180mm	400ml
4	Extra Large (XL)	140mm	≈ 85 mm	210mm	700ml

5.2 Technical Specification for Deployer Handle

Sr. No.	Description	Size
1.	Deployer Handle (S, M, L, XL)	10mm [Diameter]

6.0 SCHEMATIC VIEW

6.1. For EzCatch YR variant (Please refer figure no.1):
A. Retrieval Bag
B. Wire
C. Deployer Handle
D. Pusher

6.2. For EzCatch TR variant (Please refer figure no.2):
A. Retrieval Bag
B. Thread
C. Deployer Handle
D. Pusher

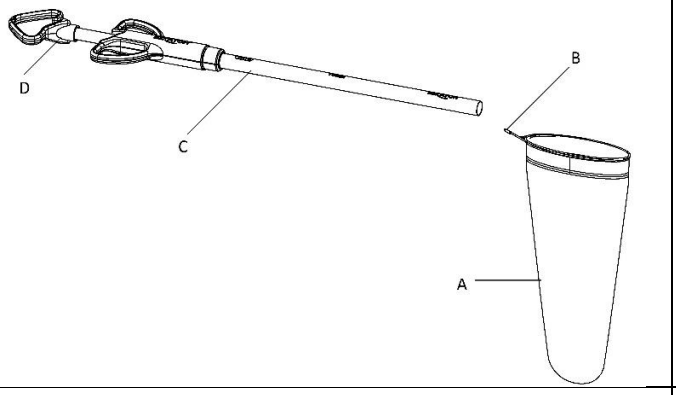


Figure No. 1 - EzCatch YR variant

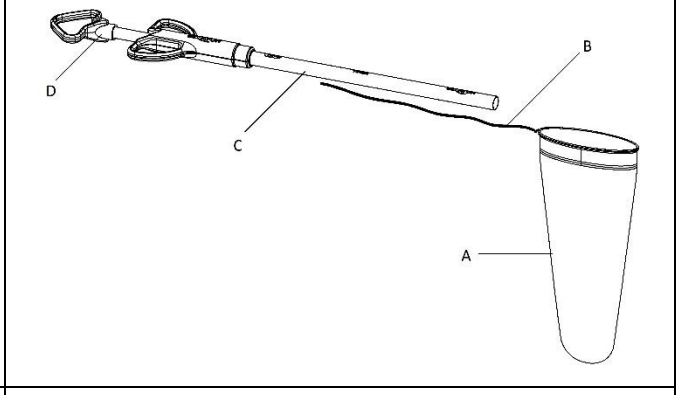


Figure No. 2 - EzCatch TR variant

7.0 PROCEDURAL STEPS

7.1 To remove a disposable EzCatch Tissue Retrieval Bag from its sterile package, peel the chevron seal of the Tyvek pouch and proceed with the instructions below.
7.2 Remove the safety lock (1) from the device as shown in Fig A.
7.3 Insert the instrument through a trocar sleeve (10mm) (2) as shown in Fig B. Voluntarily open the trocar flap (3) whenever required while inserting the device through the trocar.
7.4 Ensure the tip of the deployer/outer tube has cleared the trocar sleeve. Push the pusher (4) forward so that the bag is advanced into the cavity as shown in Fig C.
7.5 Remove the deployer handle (5) from the trocar sleeve and discard the same.
7.6 Manipulate the opening of the EzCatch bag (6) using grasper if required as shown in Fig D.

7.7 Place specimen (7) into the bag (Fig E). Once the specimen is completely within the bag, pull the end of the thread (8) (in case of TR variant) or the end of the wire (8) (in case of YR variant) with grasper to close the mouth of the bag (refer to Fig F).

7.8 To remove the EzCatch Bag from the cavity, use grasper to pull the top of the bag through the distal end of the trocar sleeve.

7.9 Once the mouth of the bag is visible at the incision site, withdraw the trocar sleeve and continue removing the bag from the incision under direct vision (refer to Fig G, H, I).

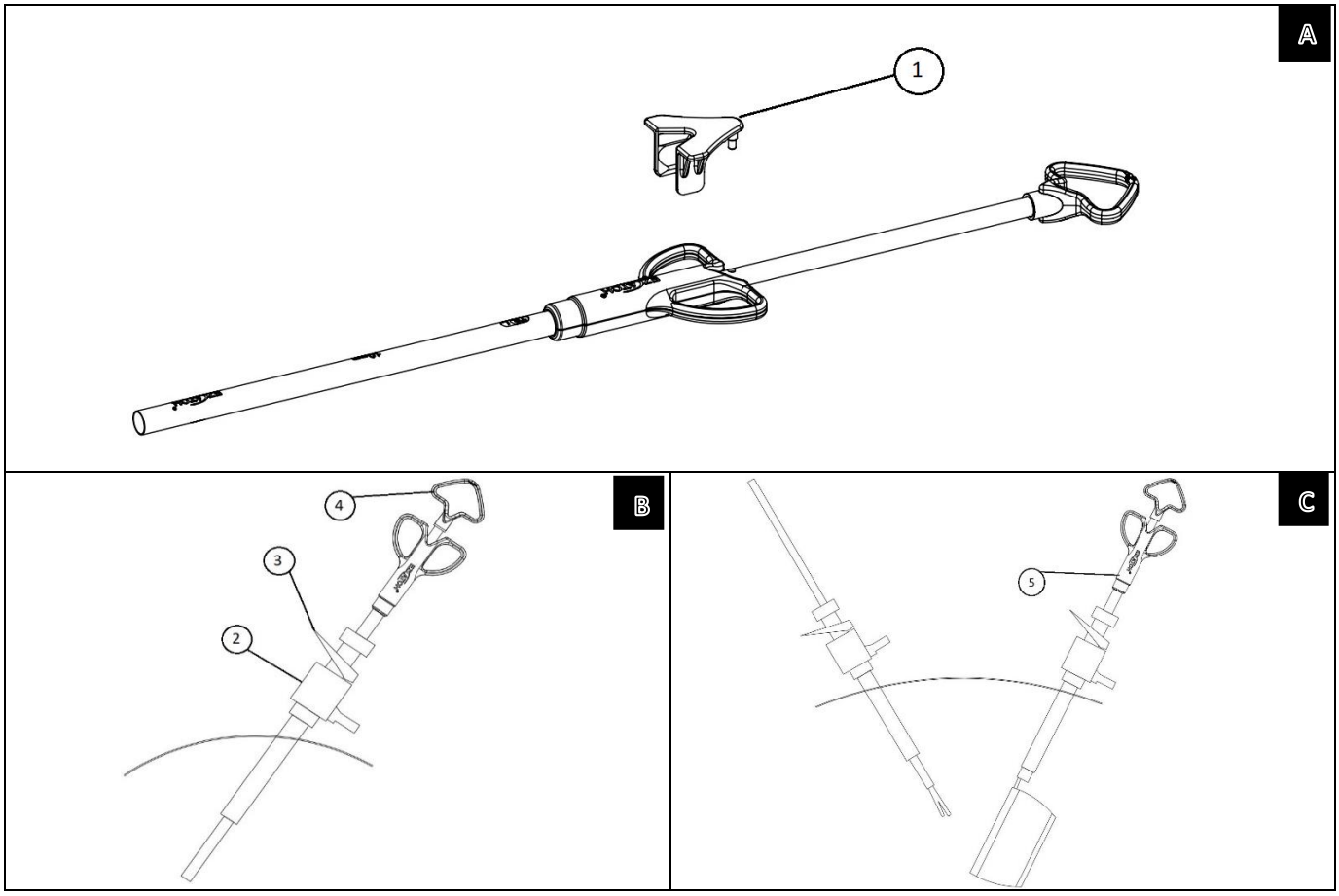
7.10 If the specimen size is bigger than the incision then cut the specimen manually to remove the bag from the body cavity. While doing so, take care that manual cutting of the specimen does not cut the bag.

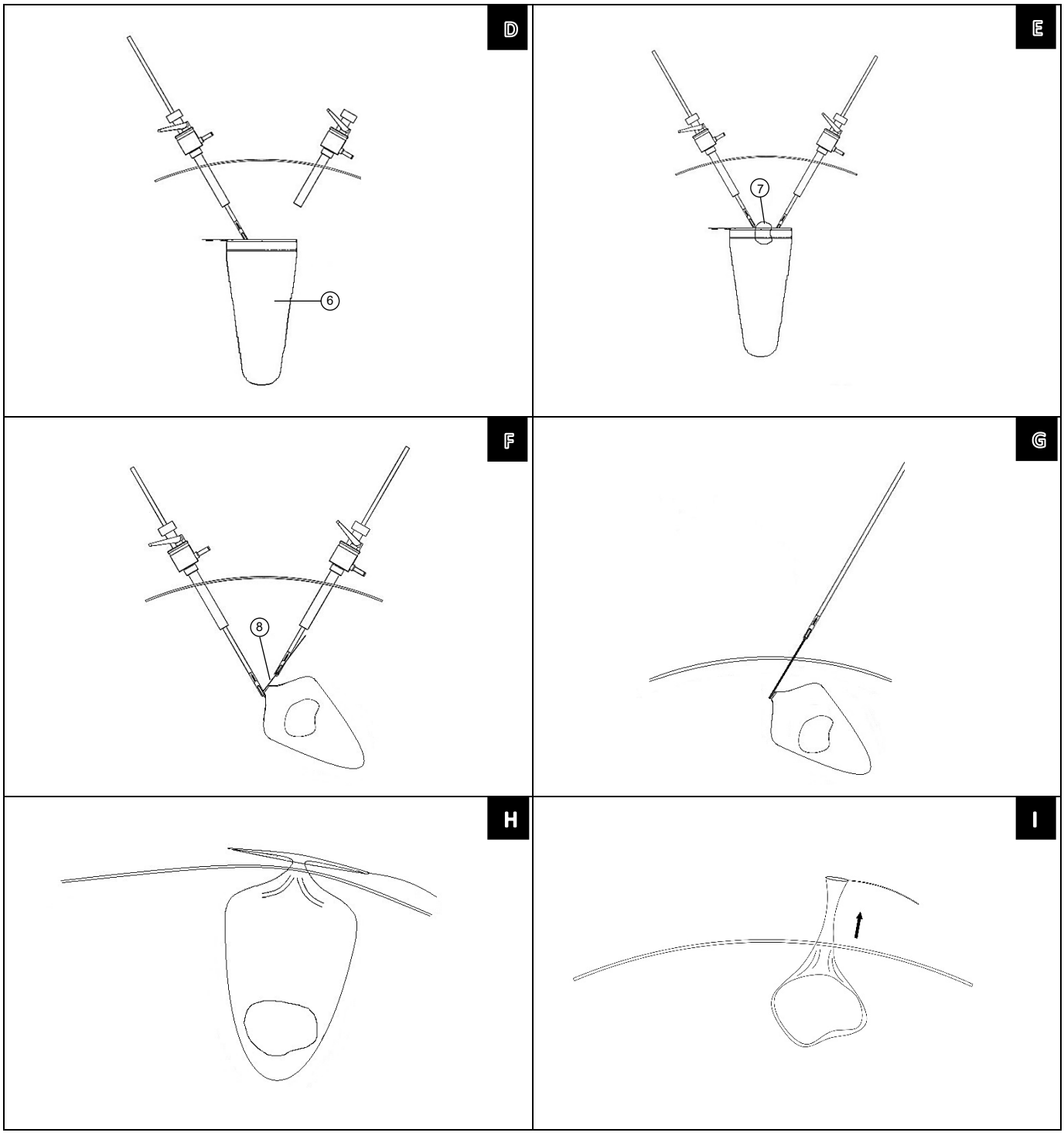
Note:

- If air is trapped in the bag, use an atraumatic instrument (surgical grasper) to enlarge the neck of the bag to allow air to escape.

8.0 DISPOSAL

Dispose the used device as per standard procedure of the hospital, administration and/or local government policy.





9.0 HOW SUPPLIED

The EzCatch (YR-TR) Tissue Retrieval Bag is packaged in peel-open Tyvek™ pouches. The product is supplied sterile and is intended for one-time use.

Do not use if the packaging of the product is damaged or opened. Store EzCatch in a dry and cool place. Avoid extended exposure to light. Upon removal from package in an aseptic or sterile area, inspect the product to ensure no damage has occurred.

10.0 TRANSPORT, STORAGE AND CARE CONDITIONS

Transport and Store EzCatch (YR-TR) Tissue Retrieval Bag in a clean and dry area away from the direct sunlight.

- Storage: (+15°C to + 30°C) & (59°F to 86°F)
- Transportation: -10°C to + 60°C.

After use, dispose EzCatch and its packaging in accordance with hospital, administrative and/or local government policy.

EzCatch (YR-TR) Tissue Retrieval Bag is packaged as a STERILE device. EzCatch (YR-TR) Tissue Retrieval Bag is intended for one-time surgical use only. Do not reprocess, re-use or re-sterilize EzCatch (YR-TR) Tissue Retrieval Bag.

Caution:

- Avoid prolonged exposure to elevated temperatures.
- Do not attempt to pull bag through trocar or outer tube of the instrument.
- Do not attempt to pull specimen bag through trocar sleeve.
- Federal law restricts this device to sale by or on the order of a physician