LapEz™

Laparoscopic Training System

INSTRUCTIONS FOR USE

Manual for Installation and Maintenance

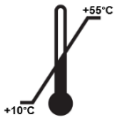
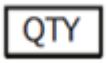
REFER TO INSTRUCTION MANUAL/ BOOKLET.

 | www.veolmedtech.com

Table of Contents

Symbols

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

	**Consult Instructions for use**
	**Date of Manufacture**
	**Manufacturer** Veol Medical Technologies Pvt. Ltd. A-747, Near Pavan Bus Stop, MIDC Pawane, TTC Industrial Area, Koparkhairane, Navi Mumbai 400705. Maharashtra, India. Ph: +91-882-882-0407 Email: info@veolmedtech.com Website: www.veolmedtech.com
	**Do not use if package is damaged**
	**Keep away from direct sunlight**
	**Keep dry**
	**Storage Temperature is between** +10°C to +55°C
	**Caution** See instruction for use
	**Expiry date**
	**Quantity**
	**Lot Number**
	**Do not dispose in garbage**

Date of Initial Issue: 15-03-2024
Date Of Revision: 28-05-2024

LapEz™

Instructions For Use

Please read all information carefully

The Instructions for Use (IFU) manual is intended to act as a technical guideline and not as a training manual. We urge Users to receive adequate training before using the device.

The Users 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 procedure.

1. General Information

1.1 Introduction

LapEz™:

- LapEz™ laparoscopy training system is designed to simulate the near live laparoscopy environment and can be practiced with real surgical instruments.
- It is a non-medical device, which bridges the gap between training and real surgery.

GEM:

- GEM *(Gargi's Engineered Model)* is a synthetic tissue model created by Veol Medical Technologies, designed to closely mimic human tissue for surgical simulation.

Fig 1. GEM

2. Device Description

Indications on the LapEz™ and its interpretation

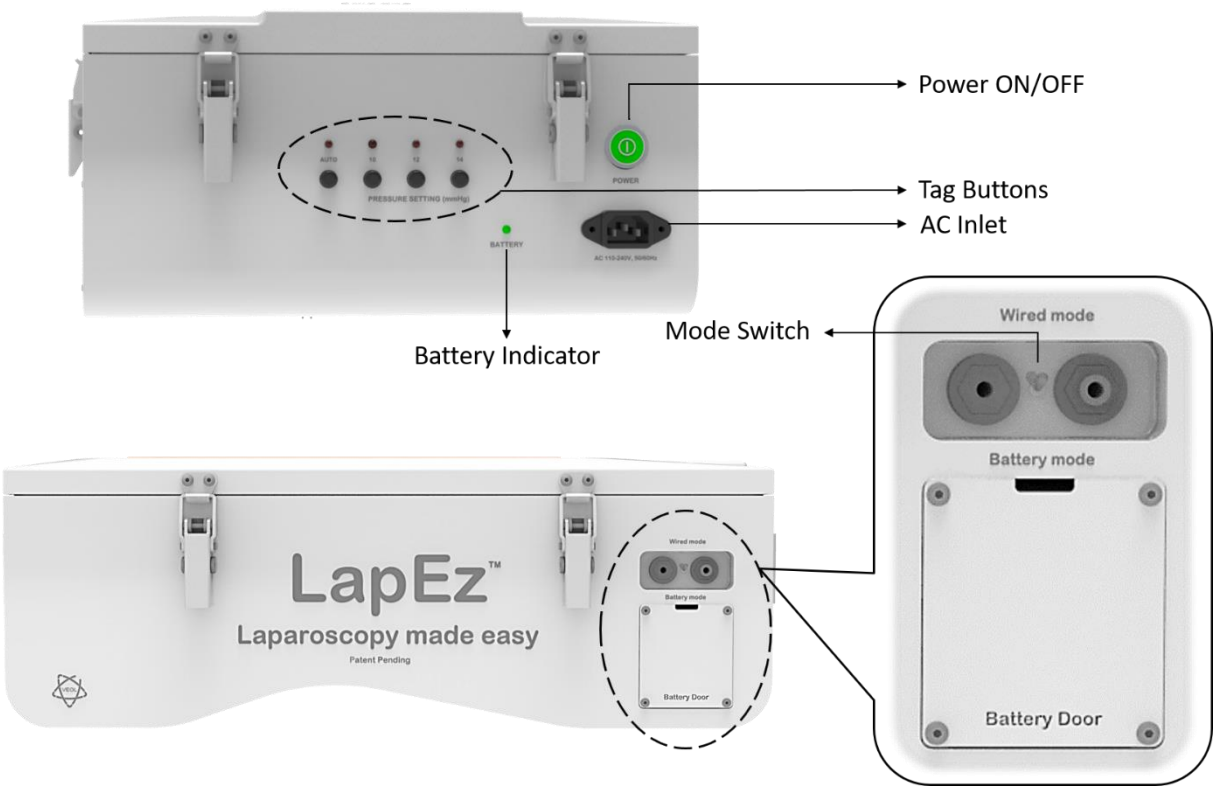


Fig 2. LapEz™ Description

2.1 Push Button *(Power ON/OFF)*

When the system is turned ON and the push button is pressed, it glows green to indicate that the system is ON.

2.2 Pressure Setting and Battery Indicator

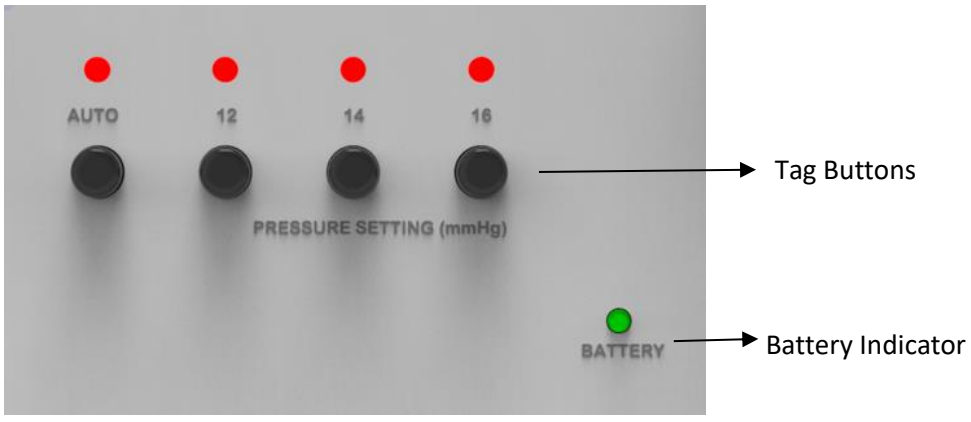


Fig 3. Tag Buttons and Battery Indicator

2.2.1 Tag Buttons

Preset Pressure Level –

Tag buttons are used for adjusting the pressure to 12mmHg, 14mmHg, or 16mmHg in order to insufflate the cavity*. Refer Fig 3*.

AUTO –

The Auto mode can be used for quick insufflation, which overrides the pressure setting and fills up the cavity quickly. *Refer Fig 3.*

Note: *In Auto Mode, the user needs to keep the button pressed until the desired insufflation level is reached and on releasing the button, it will return to its default settings.*

2.2.2 Battery Indicator

Battery indicator displays remaining battery life when power cord is unplugged *(Refer Fig 2)*:

- Green colour indicates that the battery is more than 70% charged.
- Red colour indicates that the battery is between 30% to 70% charged.
- Red led will blink if the battery is less than 30% charged and the device will turn OFF to avoid deep drainage of battery.
- There will be no Indication when system is running in AC power.

2.3 Operating Modes

The Mode switch is used to select mode of operation i.e. Wired Mode or Battery Mode. *(Refer Fig 2)*

- ***Wired Mode****:* On selecting the wired mode, the device will operate through direct AC Supply.
- ***Battery Mode****:* On selecting the Battery Mode, the device will use battery power to operate.

3. Contents of the LapEz™

Part name	**Part code**	**Qty.**
Top lid with LAW (Detachable part)	LZ-4000	1 no.
LapEz™ Box		1 no.
Power Cord (Detachable part)		1 no.
Insufflator Tube (Detachable part)		1 no.
Allen key		1 no.
Extra Wing Nuts		4 no.
Plug		2 no.
18650 Lithium-ion battery (Optional)		6 no.

3.1 Top lid with LAW (LapEz™ Abdominal wall)

The Top lid assembly is formed by fastening the Top lid and LAW together using the wing nut.

In LAW, *Umbilical Port* is marked with Label for usage. LAW can easily accommodate additional ports and features can be customized according to specific needs. The hooks on the top lid are designed for seamless integration with the latches of the Box.

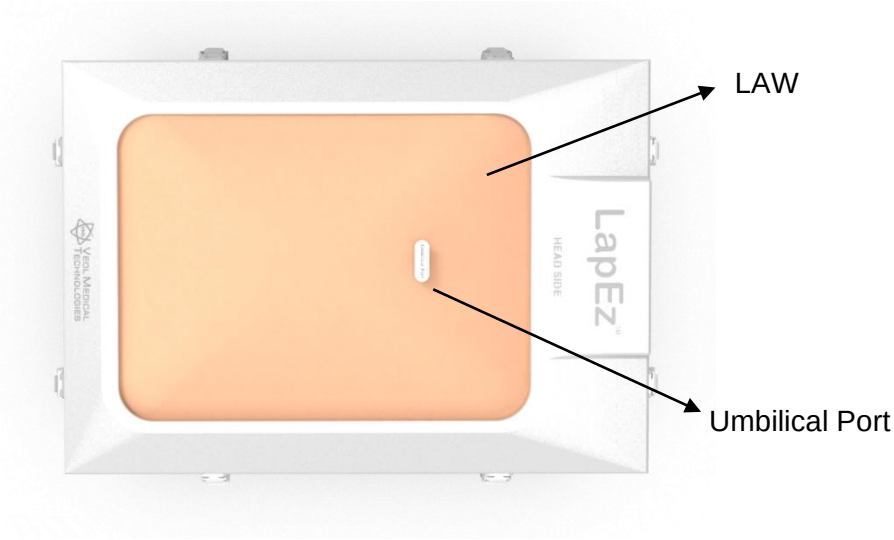


Fig 4. LapEz™ Top Lid

3.2 LapEz™ Box

- The LapEz™ Box contains Insufflator pump and other supporting electronic parts that are powered by a power source or Lithium-Ion batteries. It has indications for Pressure settings, Power and Battery.

- Tag buttons are used to adjust the pressure to 12mmHg, 14mmHg, or 16mmHg to insufflate the cavity.

- The Auto mode can be used for quick insufflation, which overrides the pressure setting and fills up the cavity quickly.
  Note: *In Auto Mode, user will need to continuously press the tag button until the desired insufflation level is reached and it will return to its default settings when the Auto Mode is released.*

- Remove the Battery Door from the LapEz™ Box to insert Lithium-Ion batteries into the battery casing.

- 18650 Lithium-Ion batteries 2200mah, 3.7V are recommended to be used in LapEz™.

- When the device is operating in the battery mode, the battery indicator will display either green or red based on the charge present in battery. The indicator will show green if the charge present in battery is above 70%. If the charge is between 30-70%, the indicator will be red, and if it falls below 30%, the indicator will blink and shut down the device as a safety measure to prevent deep draining of the batteries. In wired mode, there will be no battery indication as the device will be powered directly by the main supply.

Fig 5. LapEz™ Box

3.3 Power Cord

Country specific Power Cord will be provided with LapEz™.

3.4 Battery

Six numbers of 2200mah, 3.7V 18650 Lithium-Ion batteries are used to power the Unit.

3.5 Insufflator Tube

The insufflator tube connects the LapEz™ to the trocar to inflate the cavity with air

Fig 6. Insufflator Tube

3.6 Plug

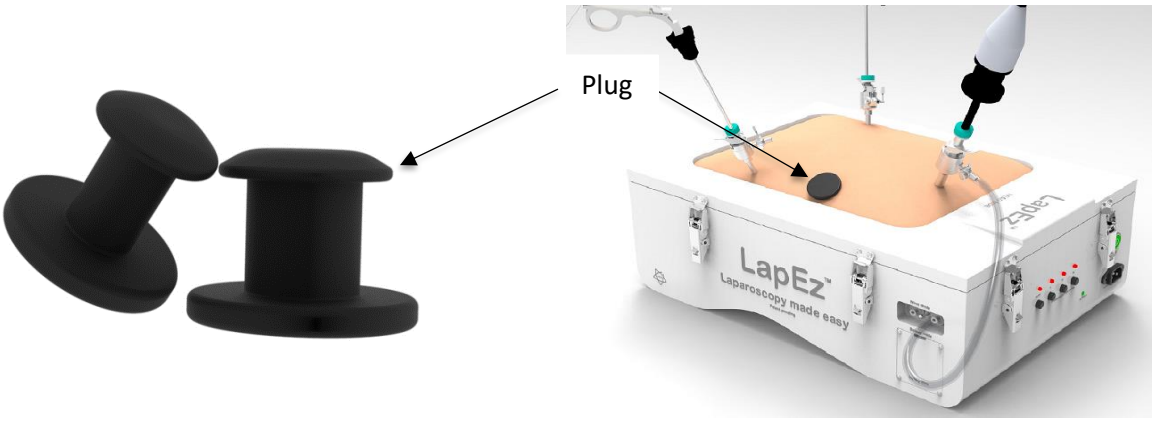


Fig 7. Plug

Large and small size plug is used to prevent air leakage from the respective size holes in LAW.
Note: *The side with the smaller diameter should be inserted into the LAW, as illustrated in the figure*

4. Assembly

The system can be run solely on mains power or it can be run on a battery.

4.1 Remove the LapEz™ box Battery Door *(Refer Fig 2)* by using the Allen key provided with LapEz™ and insert the 6 nos of Lithium-Ion batteries into the battery casing inside the box.

Note: *Check the positive and negative markings on the battery and casing for appropriate placement before inserting the batteries into the battery casing.*

4.2 Connect the power cord to the AC inlet. *Refer Fig 2.*
Cover with the top lid (Make sure the head side of LapEz™ Lid and electronics sides are aligned), ensuring all eight latches are locked. *Refer Fig 8.*

Note: *Ensure the lid is properly aligned with the latch on the box.*

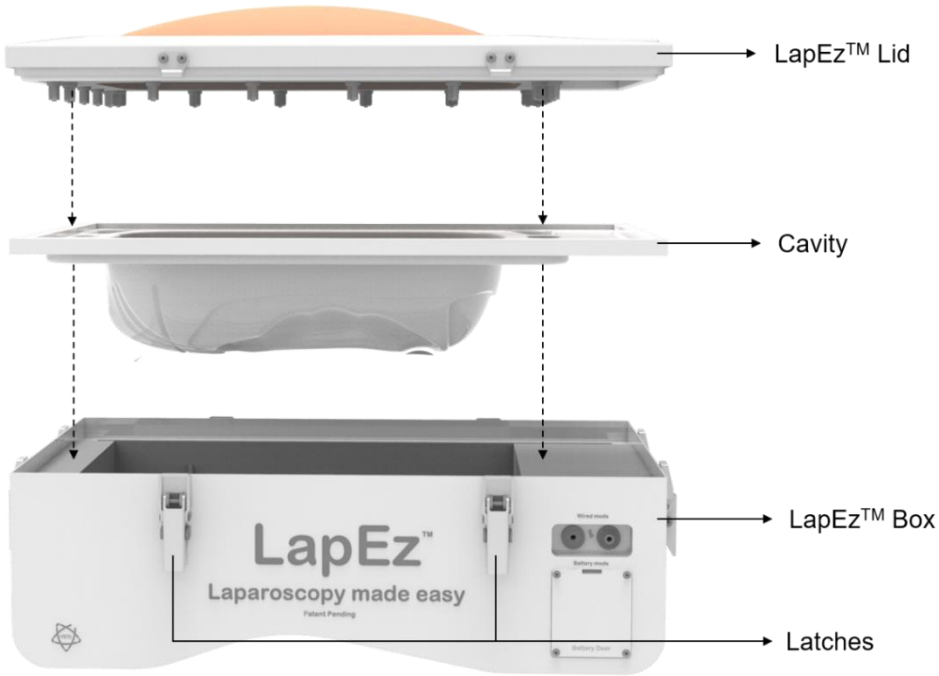


Fig 8. LapEz™ Unit Assembly

5. Instructions for Use

5.1 Connect one end of the Insufflator tube to the insufflator output of LapEz™ and the other end of the tube to a trocar with luer lock. *Refer Fig 9.*

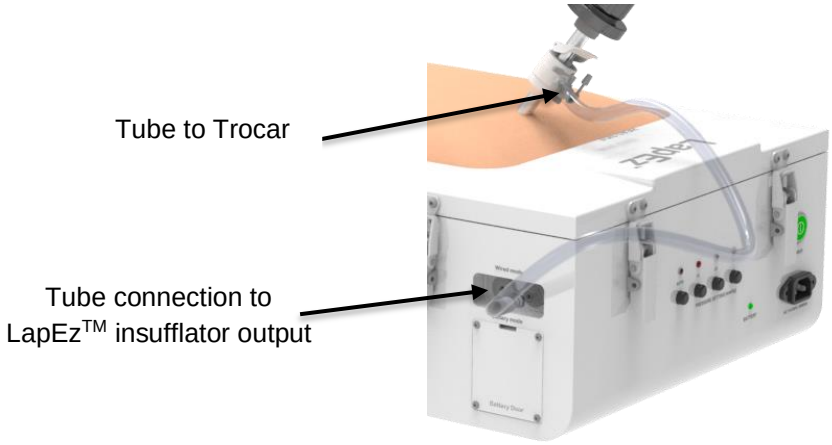


Fig 9. Tube Connections

5.2 Create a Port in the LAW by inserting a trocar through the umbilical port mark provided in the LAW, or create a custom port using a trocar. *Refer Fig 10.*

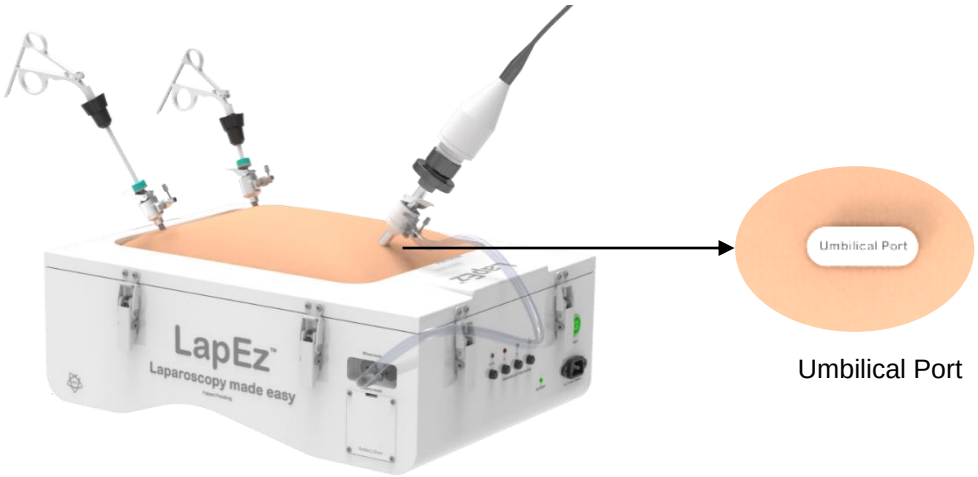


Fig 10. Umbilical Port

5.3 Choose the mode of operation, using the switch, before turning ON the system by selecting either Wired Mode or Battery Mode. *Refer Fig 11.*

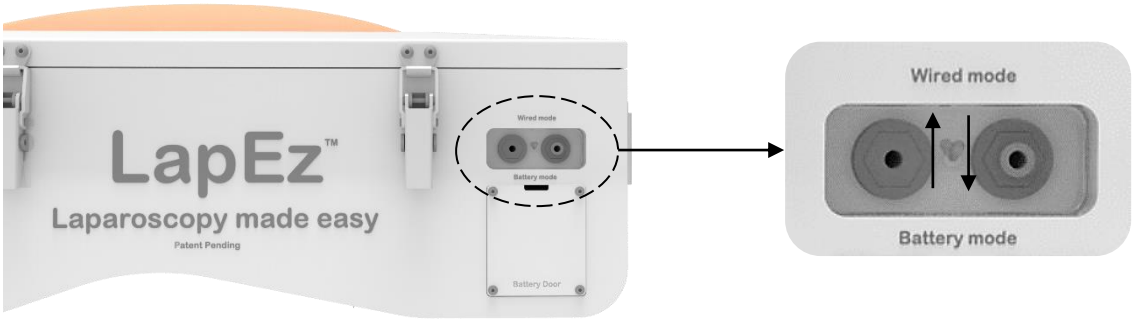


Fig 11. Mode Switch

5.4 If the operating mode is selected as Wired Mode, then switch ON the Mains first then press the Power ON/OFF button. *Refer Fig 2.*

5.5 If the operating mode is selected as Battery Mode, then only press the Power ON/OFF button.

5.6 To insufflate the LapEz Abdominal Wall *(LAW)*, select the pressure setting from 12mmHg, 14mmHg, or 16mmHg, or Auto mode. *Refer Fig 2.*

5.7 The Auto mode can be used for quick insufflation, which overrides the pressure setting and fills up the cavity quickly.
Note: *While using Auto Mode, you must consistently press the tag button till the desired insufflation level is achieved. The device will revert to its default settings as soon as Auto Mode is released.*

6. Parts Replacement

6.1 LAW Replacement

To remove the LAW from the Lid of LapEz™, unscrew all Wing nuts anticlockwise. If the LAW has been used ten times or if there is any leakage in the cavity, replace it with a new one, ensuring that all holes are aligned, and then secure it in place by tightening all Wing nuts in a clockwise direction. *Refer Fig 12.*
Note: *Ensure that the white PC sheet (Hard Surface) of the LAW is facing upwards when attaching it with the LapEz™ lid and apply pressure to compress the LAW while tightening the wing nut.*

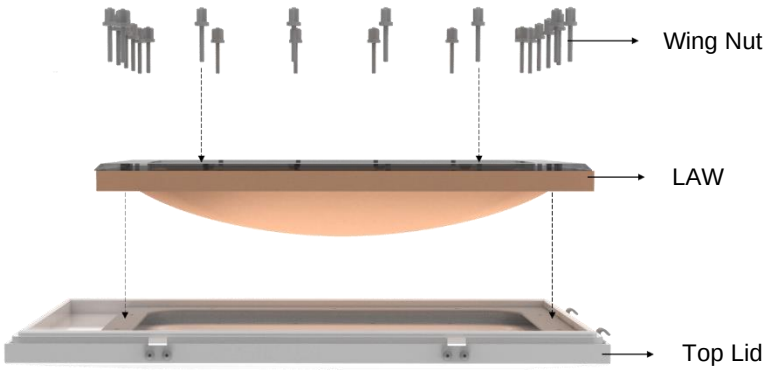


Fig 12. LAW Placement

6.2 Cavity Replacement

The Cavity inside the LapEz™ unit can be replaced when required. Remove the Top Lid from the box by unlocking the latches and carefully remove the cavity by holding the slots in the cavity. Place the new cavity by holding the slotted area and gently press along the sides of cavity so that it is placed properly. *Refer Fig 13.*

Fig 13. Cavity Placement

7. Operating Principle

LapEz™ utilizes advanced technology to provide controlled insufflation of the abdominal cavity through the use of suctioned air.
The instruments are inserted through the simulator's inflated abdominal wall to carefully remove GEM (artificial tissue) through morcellation.

8. Technical Specifications of LapEz™

Physical	Weight	approx. 12.5 kg
	Dimensions	approx. 500mm x 353mm x 187m (L x W x H)
Electrical	Rated voltage, frequency	100-240 VAC, 50-60 Hz
	Maximum power drawn	93.5W, 6.23 A
Battery (Optional)	***18650 Lithium-ion***	6 Nos.
Functional	Pressure Setting	Auto 12mmHg 14mmHg 16mmHg
Power Cable	Length	Country specific

9. Basic troubleshooting

Sr. No.	Issues	Checkpoints for rectification
1.	The Push Button does not glow	• If in battery mode, switch to wired mode in order to check whether the presence of any battery-oriented issue. • Ensure that proper connection is established between the main's supply and AC inlet present on the LapEz™ box.
2.	Failed insufflation of cavity	• Check the LAW for major air leakages • Examine the cavity for any signs of damage. • Allow the system to cool down for a while and restart again
3.	System fails to start in Battery Mode	• Check the Battery orientation • Change the battery and restart system Note: If issue persists in Battery mode, select the wired mode and use with direct mains supply.

Note: *In case any of the issues persists even after following the respective checkpoints, the service personnel should be contacted.*

10. Additional Accessories

Component Name	Product code
LapEz™ Abdominal Wall (LAW)	LZ-4060
GEM - Synthetic fibroids	LZ-4010
10mm Trocar (Recommended: Applied medical/ or any optical trocar)	LZ-4030
5mm Trocar (Recommended: Applied medical)	LZ-4040
10mm Tenaculum	LZ-4040
5mm Fenestrated Grasper	LZ-4050
Portable Endoscopy System	LZ-4070
0^o 10mm Endoscope	LZ-4080
30^o 10mm Endoscope	LZ-4090

Note: *Accessories will be supplied with the LapEz™ as per the requirement.*

11. Transport, storage, care and maintenance

11.1 Use and Maintenance

The LapEz™ Unit should be stored in a cool and dry place. Do not spray, drop or immerse LapEz™ in liquid. The LapEz™ Unit should be used at operating temperatures mentioned below:
Temperature: 15ºC to 30ºC.

11.2 Storage and Transportation

The LapEz™ Unit can be transported, stored under following conditions:
Storage: +10ºC to +55ºC
Transportation: +10ºC to +60ºC

The GEM can be transported, stored under following conditions:
Storage: 20 ºC to 25 ºC
Transportation: +10ºC to +40ºC
Shelf Life: 6 months

12. Warnings & Precautions

12.1 General Instructions

12.1.1 The Instructions for User manual should be thoroughly studied and ensured that all the instructions given in this user manual are followed while using the device.
12.1.2 Store the LapEz™ in a clean, dry area away from the direct sunlight and at room temperature.
12.1.3 LapEz™ is an electrical device that should be handled with care. It is meant for use by well trained professionals only.
12.1.4 Before using the device, make sure to thoroughly examine all equipment's, instrumentation, and cables for any signs of wear & tear or damage. If any issues are found, do not try to use the device. Instead, reach out to the distributor or field service technician for help with repairing or replacing the damaged components.
12.1.5 Use only non-flammable materials when cleaning the LapEz™.
12.1.6 LapEz™ does not require any special installation except steady power.

12.1.7 No modification of this equipment (i.e. LapEz™) is allowed.
12.1.8 No maintenance should be carried out while LapEz™ is in use.
12.1.9 User should not use any other power cable than that supplied by manufacturer.
12.1.10 In case of failure, contact the distributor or field service technician for assistance regarding repair or replacement.
12.1.11 Use original packaging of device for any transportation if any required in Product Service Life.
12.1.12 Product is fragile and should be handled with care.
12.1.13 The packages during transportation should be handled with care.
12.1.14 The packages should not be exposed to direct sunlight or rain.
12.1.15 Transportation temperature should be maintained as mentioned above.
12.1.16 The packages should be safeguarded from any contamination, such as chemical vapours, pesticides, undue dust, insects and pests.

12.2 Unpacking and General Instructions

Remove all components carefully from the shipping carton and check all components to ensure they have not been damaged during shipment.
All the contents of the carton have to be thoroughly checked for any signs of damage.
In case any damage is found, contact the shipping company or distributor immediately.

12.3 Operational Condition

The whole procedure, using the LapEz™, should be carried out in ambient atmospheric condition in a training centre.

12.4 Cleaning/Reuse

Always keep the LapEz™ clean and dry. The LapEz™ can be reused many times but it should be cleaned after every use. Spilled fluids may be wiped clean from the Cavity and LAW with Dry/Wet cotton swab.

12.5 Safe disposal

- For disposal of LapEz™ after its 3 years' service life, ensure compliance with administrative policy and/or local government policy or it is recommended to avail services of Professional junk remover service provider to haul away junk in a safe and environmentally responsible manner.
- GEM should be disposed as per country specific regulations for plastic.
- Batteries should be disposed as per country specific requirements.