



Command Unit (CU) For AutoLap User Manual

CE 1023

- **Device name**

Command Unit Clip EU Part Number: ASS02001
Command Unit Clip US Part Number: ASS03001
Command Unit Ring EU Part Number: ASS04001
Command Unit Ring US Part Number: ASS05001

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CHAPTER 1. General

1.1 Introduction

This manual is an accompanying document to the Command Unit (CU) – control components of the AutoLap system. The AutoLap system is designed to hold and control the movement of the laparoscope during laparoscopic surgeries.

It describes the Command Unit, as well as its functioning as part of the AutoLap system.

1.2 Scope of This Manual

The scope of this user manual is to provide the safety information of the product, and to explain the basic operating instructions that are performed by the system's user.

1.3 Conventions Used in this Manual

The following symbols and conventions are used in this manual:

 Note	Notes provide plain good advice and/or additional information of which the user should be aware. A note is located next to the relevant text and should not be used for direct action.
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 Caution	Alerts the user to a possible problem with the device concerning its use or misuse. Such problems include device malfunction, device failure, damage to the device or damage to other property. The caution statement includes the precaution that should be taken to avoid the hazard.
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 Warning	Alerts the user to the possibility of injury, death, or other serious adverse reactions associated with the use or misuse of the device.
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Explanation of Shortcuts in this manual user:

CU – Command Unit

DOF – Degree Of Freedom

OR – Operating Room

EMC – Electromagnetic Compatibility

IEC – International Electrotechnical Committee

CHAPTER 2. About the CU

2.1 Intended Use

The Command Unit (CU) is a sterile disposable unit that is designed to transmit low power RF signals. The main functions of the RF signals are to enable the movement of the laparoscope to the surgeon's desired location.

2.2 The CU Modes of operation

The CU is designed to control the movement of the laparoscope at the discretion of the surgeon. Pressing the button of the CU will start the movement of the laparoscope. When the surgeon stops pressing the button, the movement is stopped.

The CU contains a Five-Way Button. Pressing the button in its different modes enables the AutoLap to move the laparoscope up or down as presented on the surgeon's screen, move the laparoscope to the right or to the left of the screen, advance the laparoscope into the patient's abdomen (zoom in) or extract it from the patient's abdomen (zoom out).

2.3 The CU Configurations

The CU is designed in two configurations :

1. **Ring**, which is worn by the surgeon on one of his fingers (like a normal ring), over the glove. The Ring Unit is activated with the surgeon's thumb. See Figure 1.

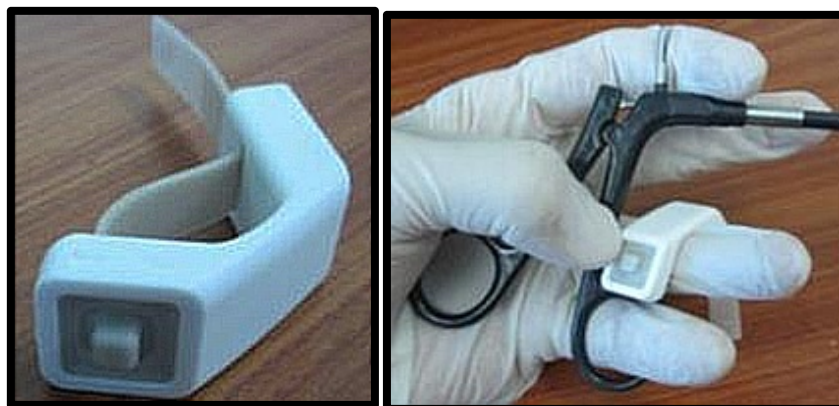


Figure 1: CU Ring configuration

2. **Clip**, which is connected to the surgical tool. The **Clip** Unit is activated with the surgeon's index finger. See Figure 2.

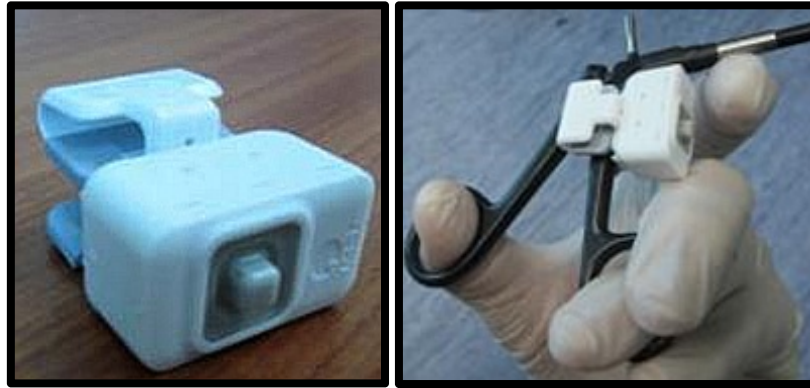


Figure 2: Clip- configuration of the CU

Both configurations contain the same inner components, and the user may select which configuration to work with.

The Command Unit is packed in a sterile blister and is a single use device.

2.4 Protection against radio frequency interference

For US only: The CU has been tested and found to comply with the limits according to the following:

CU Ring FCC ID: OSEALRU

CU Clip FCC ID: OSEALCU

Manufacturer: MST Ltd.

This device complies with Part 15 of the FCC Rules.

Operation is subject to the following two conditions:

- (1) This device may not cause harmful interference
- (2) This device must accept any interference received, including interference that may cause undesired operation.

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help

 Warning	Changes or modifications to this equipment not expressly approved by the party responsible for compliance [Medical Surgery Technologies Ltd. (MST)] could void the user's authority to operate the equipment.
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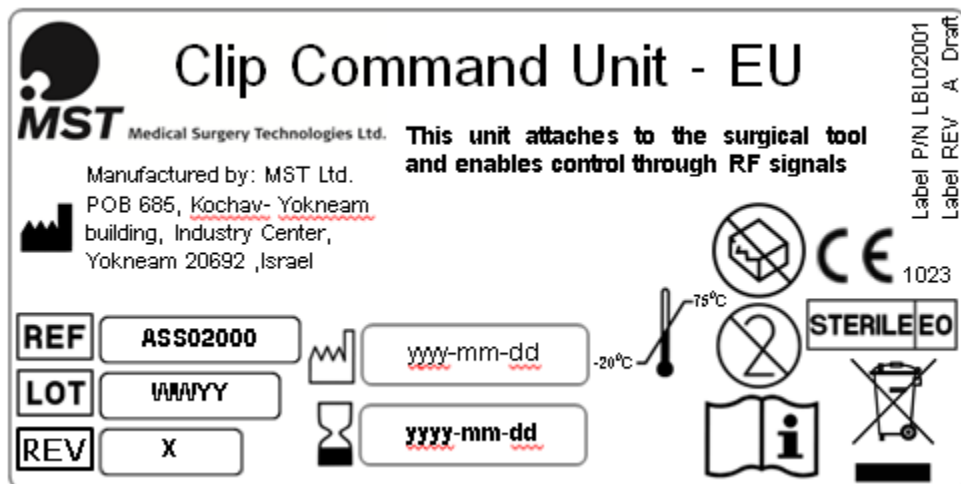
CHAPTER 3. Contents of the Sterile Package

The CU sterile packaging consists of a blister which is closed by TYVEK. This package is called the unit package.

Six (6) unit packages are packed in a cardboard box, called the storage package. Six (6) storage boxes are packed in a bigger cardboard box, which is the transportation package. During storage either transportation package or storage package can be used.

The CU is sterilized using EtO.

The labels affixed on the unit blister packages are depicted below.





Ring Command Unit - EU

Medical Surgery Technologies Ltd.

This unit attaches to the surgeon's finger and enables control through RF signals

Manufactured by: MST Ltd.
POB 685, Kochav- Yokneam
building, Industry Center,
Yokneam 20692 ,Israel

Label P/N LBL04001
Label REV A - Draft

REF ASS04000

LOT WWWW

REV X

75°C

-20°C

STERILE EO

1023



Clip Command Unit - US

Medical Surgery Technologies Ltd.

This unit attaches to the surgical tool and enables control through RF signals

Manufactured by: MST Ltd.
POB 685, Kochav- Yokneam
building, Industry Center,
Yokneam 20692 ,Israel

Label P/N LBL03001
Label REV A - Draft

REF ASS03000

LOT WWWW

REV X

FCC ID: OSEALCU

75°C

-20°C

STERILE EO

Caution: US Federal Law restricts this device to sale by or on order of a physician.



Ring Command Unit - US

Medical Surgery Technologies Ltd.

This unit attaches to the surgeon's finger and enables control through RF signals

Manufactured by: MST Ltd.
POB 685, Kochav- Yokneam
building, Industry Center,
Yokneam 20692 ,Israel

Label P/N LBL05001
Label REV A - Draft

REF ASS05000

LOT WWWW

REV X

FCC ID: OSEALRU

75°C

-20°C

STERILE EO

Caution: US Federal Law restricts this device to sale by or on order of a physician.

Figure 3: CU Package labels

CHAPTER 4. Handling

4.1 On Receipt of Package

The unit package should be inspected on arrival. If any damage is observed in the unit package, the package must not be opened.

 Warning	Do not use the CU if the package is damaged or open.
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Check that the documentation and label description agrees with the order acknowledgment. If there are differences do not open the package, place in a secure area and notify MST.

4.2 Storage

Store the CU packages in a dry location at normal room temperature away from direct heat sources. During transit, the CU may be exposed to temperatures in the range of -25°C to +75 °C.

CU will retain its sterile status as long as the sterile package is undamaged and up to 6 months from the manufacturing date indicated on the CU's label.

4.3 Summary of Warnings and Precautions

The order in which the following warning statements are presented is not a reflection of their relative importance. Some of the warnings are specified in this chapter while others - more specific - are specified in the chapter in which their related functionality is explained.

4.3.1 Sterilization Related Warnings

 Warning	The CU is provided STERILE and is intended for use during a SINGLE procedure only. DISCARD AFTER USE. DO NOT RE-STERILIZE. If the package is found open or damaged, it must be discarded.
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 Warning	Do not use the CU if the expiration date has passed.
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4.3.2 Routine Operation and Maintenance Related Cautions and Warnings

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 Caution	The CU is to be used by licensed medical personnel. This device should only be used by a practitioner fully trained in the conventional operative Laparoscopic technique.
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 Caution	Dispose of used CU according to the common procedures for disposing batteries of the hospital
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CHAPTER 5. Technical Characteristics

Command Unit (CU) Ring		
	Dimensions	49mm (H) * 16mm (W) * 24mm (D)
	Weight	9 g

Command Unit (CU) Clip		
	Dimensions	34mm (H) * 17.4mm (W) * 27mm (D)
	Weight	10 g

CHAPTER 6. CU Operation

6.1 Attaching the CU to finger or tool

#	Action	Demonstration
1	Open the CU Ring or Clip blister according to the chosen configuration	

Pull

2	If the CU Ring is used, wear it on the appropriate finger at a convenient location and pull its strip to tighten it. Tighten the strip such that the device will not move when its button is pushed sideways.	
3	If the CU Clip is used, attach it to the appropriate tool by pressing the Clip against the edge of the tool. The width of the Clip can be adjusted to fit different sizes of tools. This can be accomplished by pressing the clip ears towards each other, until the clip is attached tightly to the tool. The clip can be released by pulling its ears apart.	