



MOFIXX

Instructions for use - Mofixx trocar and obturator

CE0344

Manufacturer:

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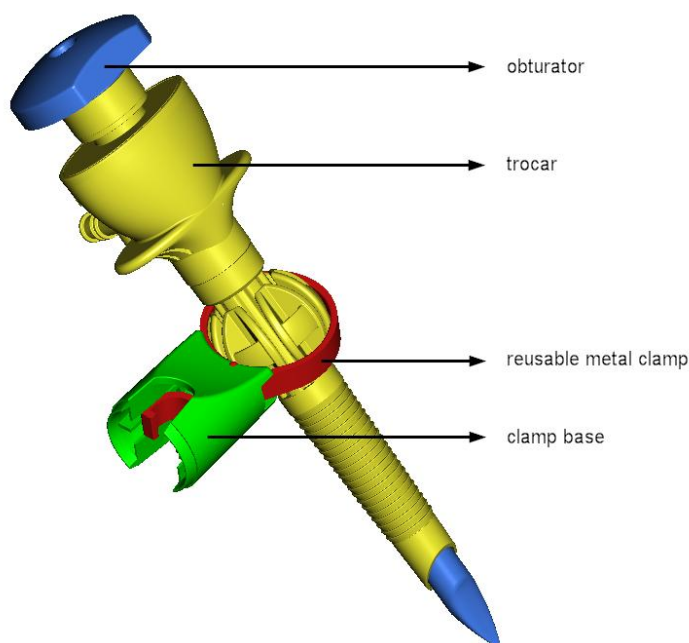
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1 INTRODUCTION

The Mofixx trocar set is intended to use with the Mofixx device and contains the following parts:

- trocar
- obturator
- clamp base.

When using the trocar in combinations with the Mofixx system, the clamp base and reusable metal clamp should be preassembled with the trocar, see picture below. Instructions on how to assemble can be found in the Mofixx user manual which is delivered together with the reusable parts of the device. This instruction for use provides the instructions necessary to operate the Mofixx trocar and obturator in accordance with its function and intended use.



Observance of this manual is a prerequisite for proper performance and correct operation, and ensures patient and operator safety. Mofixx is responsible for safety, reliability and performance of this product only in the condition that:

- The product is operated under strict observance of this manual.
- The product is not damaged.
- The packaging is not damaged



Do not use the product without carefully reading the instructions for use.

In the event that it becomes necessary to return a unit to Mofixx, please contact the Mofixx Service Department of your local sales agent. Please provide the catalogue number and batch code together with a brief description of the reason for return. The customer is responsible for freight charges when this product is sent to Mofixx for service (including any relevant customs fees or other freight related charges).

Statement:











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2 INTENDED USE

The Mofixx sterile disposable trocars are intended to establish a port of entry for endoscopic cameras and instruments used during laparoscopic procedures. The trocars are intended to use in combination with the Mofixx system that fixates the laparoscope/instrument inside the trocar. However it can also be used without the Mofixx system.

3 EXPLANATION OF SYMBOLS AND SAFETY NOTES

3.1 Symbols

Symbol	Explanation
CE 0344	CE mark
	Manufacturer
	Catalogue number
	Batch code
	Use by date
	Not to be used in case package is damaged
	Latex free
STERILE EO	Sterilized using ethylene oxide
	Protect from rain
	Caution, consult documents
	Read usage instructions
	Re-use not allowed

3.2 Safety notes

The following safety notes are used in this manual to support the text:



Warning: Read the statement below the symbol. The statement alerts you to an operating hazard that can cause personnel injury.



Caution: Read the statement below the symbol. The statement alerts you to possible damage to the device or other property.



Note: Read the statement below the symbol. The statement alerts you to a possibility of operating table damage or unreliable analysis results.

4 DESCRIPTION

The Mofixx trocar is equipped with a sealing system for maintenance of pneumoperitoneum during insertion and withdrawal of instruments and with a luer stopcock port for insufflation and desufflation of operative cavity. The Mofixx Obturator is conducted with a bladeless configuration. Product shelf life is 3 years.

Series	Specifications	Picture
Disposable trocar set 10 mm short	For $\varnothing 10$ laparoscope/ instrument	
Disposable trocar set 10 mm long	For $\varnothing 10$ laparoscope/instrument	

**Warnings:**

- These trocars should only be used by physicians with adequate training and familiarity with minimally invasive techniques. For further information about the techniques, complications and hazards, please consult the medical literature.
- Prior to use, read and follow the instructions of all the products to be used during the procedure. Always inspect this product carefully for overall integrity before use.
- Improper use of this product can result in life-threatening injury to internal organs and vasculature. Exercise caution during trocar insertion.
- Keep organs out of reach of trocar penetration by ensuring proper positioning of the patient's body.
- Direct the trocar away from major vessels and other anatomic structures.
- For the second and additional punctures of the trocar into the abdominal or thoracic cavity, inspect the tip of the trocar visually by monitor.
- After removing the trocar from the cavity, take appropriate steps to achieve hemostasis as needed.

**Caution:**

- Remove the trocar by using continuous upward force while gentle rotating the trocar in alternating clockwise and counterclockwise directions until these are completely visible.
- Do not use excessive force or in a manner not consistent with normal instrumentation use. This may compromise its functionality and safety.

**Notes:**

- The trocar and obturator are not intended for use when endoscopic techniques are contraindicated.
- The trocar and obturator are intended for single patient use ONLY. DO NOT RESTERILIZE. Dispose of all used product as standard hospital practices for biohazard control.
- There is no contraindication that has direct connection with the trocar and obturator till now. Physicians should have the idea whether patient can use this product according to the patient's particular situation. For further information about techniques, complications and hazards, please consult the medical literature.

5 GENERAL INSTRUCTIONS FOR USE

1. The trocar and obturator and clamp base are packaged unassembled. Assemble the trocar by inserting the obturator into the trocar cannula until they match together.
2. Assemble trocar with reusable metal clamp & clamp base according to the Mofixx user manual which is delivered together with the reusable parts of the device.¹
3. Select and follow a suitable endoscopic and/or laparoscopic protocol.
4. If the trocar is packaged with the stopcock in its open state. To prevent de-sufflation during insertion, close the valve prior to use.
5. Make a small incision where the trocar will be introduced.
6. Ensure there is no blood vessel or grume existing in incision area. Insert the obturator and trocar according to the texture level of tissue through the incision by applying continuous downward pressure until the body cavity has been completely penetrated (Figure 1).
7. To insufflate, attach a gas line to the trocar port and open its valve.
8. Remove the obturator and insert appropriately sized camera or instrument.
9. At the end of the procedure, disconnect trocar with attached clamp from Mofixx adapter. See Mofixx user manual for instructions.
10. Leave the laparoscope in place during de-sufflation and removal of the trocar. Exteriorization of the cavity contents can occur if the laparoscope is first pulled from the trocar.
11. Disassemble the reusable metal clamp from clamp base/trocar and run reusable metal clamp through CSA. See Mofixx user manual for instructions.

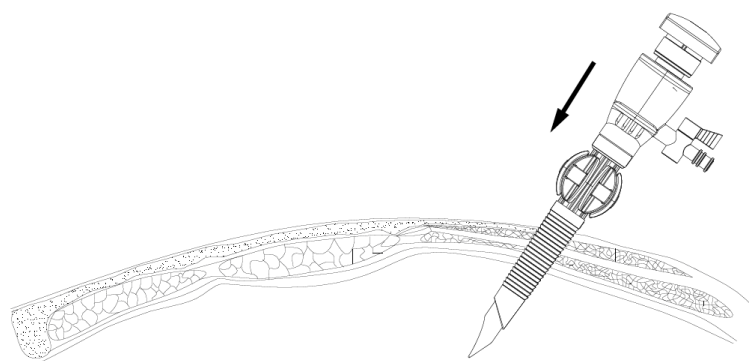


Figure 1

6 STORAGE

- Keep safe in clean environment, which is kept away from the sun, rats, fire, insects and caustic gas, as well as with good ventilation.
- Storage temperature range: -20°C ~ 50°C, relative humidity range: 10% ~ 80%.

¹ When the trocar is not used with the Mofixx system this step can be skipped.

7 CONTACT

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