

MIRAJET**CE**
0068

User manual

Article number	MJ-UM-01-001-EN
Management number	MJ-FPM-01-001-EN
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1 . Notice

This user manual is designed to guide users through the basic usage and the uniqueness of the mirajet of JSKBiomed Inc.

- 1) Please read this manual carefully before using it for any safety incidents and proper use.
- 2) This manual is based on revision date and the details of the manual are subject to change without notice.
- 3) We shall not be liable for any problems during the use of information obtained through third parties other than JSKBiomed Inc.
- 4) We assume no liability for any performance degradation or compatibility caused by users mistake or negligence.

2 . Product (item name) Overview purpose of Use

. Product Overview

This product is a disposable medicine direct injection device that injects medicines into the human body by connecting a connector to the articulated arm of the laser surgical machine and connecting a disposable syringe.

It is a mechanism for penetrating the medicine into the skin by focusing and exploding the laser into the liquid inside the cylinder to generate an instantaneous pressure, and then injecting the medicine in the chamber in the form of fine particles by the expansion of the elastic membrane.

2.1. Device Name: Sterile, single use needle-free injector

2.1.1 Purpose of Use : mirajet nozzle is intended to deliver subcutaneous or intramuscular injections of vaccines or medicines (Excluding disinfectant, medical oxygen, anesthesia gas etc.)

2.1.2 Model Name : MJNZ-1H150, MJNZ-1H200, MJNZ-1H250

Partial Product Name	Type Name	Diameter (unit: mm)
Micro Nozzles	MJNZ-1H150	0.15
	MJNZ-1H200	0.20
	MJNZ-1H250	0.25

2.2 Packing List**(1) Single use needle-free injector**

Part No.	Item	Q;ty	Remark
MJ-FP-01-001	MJNZ-1H150	1	*Option
MJ-FP-01-002	MJNZ-1H200	1	
MJ-FP-01-003	MJ-NZ1H250	1	
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(2) Connector

Part No.	Item	Q;ty	Remark
MJ-HP-10-001	MJHP	1	*Option
MJ-HP-10-002	MJHP-M	1	
MJ-HP-10-003	MJHP-F	1	

2.3 Product performance

2.3.1 Laser : Wavelength 2,940nm, Output energy 401~600mJ, Pulse width 40us, Pulse repetition rate 10Hz, Focal lens f100

2.3.2 Ejection Volume.

Chemical Liquid nozzle size	Output energy[mJ]	Standard ejection frequency [times]	Jet volume[ml]
150um	401	410	0.1
	600	280	0.1
200um	401	230	0.1
	600	150	0.1
250um	401	150	0.1
	600	120	0.1

2.3.3 Environment conditions

An anti-tree	The Tide	Remark
Operating temperature	5°C ~ 40°C	
Operating relative humidity	15% to 95% (non-condensing)	
Operating atmospheric pressure	700 to 1,060 hPa	

Storage temperature	-10C to 65°C	
Storage humidity	15% to 95% (non-condensing)	
Storage atmospheric pressure	700 to 1,060 hPa	
Transport temperature	-10C TO 50C°	
Humidity during transportation	15% to 95% (non-condensing)	
Atmospheric pressure during transportation	700 to 1,060 hPa	

2.3.4 Target treatment group and diseases

- 1) Patient condition: Immunodeficiency patient.
- 2) Target patient health or diseases: No limit

2.3.5 Contraindications

- 1) Pregnancy and lactation.
- 2) Individuals with chronic skin diseases.
- 3) Diabetes

3. How to use

3.1 Injector

3.1.1 Preparation before use

- 1) This product is fully sterilized and sealed so that it is checked for breakage or absence of packaging.
- 2) Ensure that the period of validity and the package is not damaged.
- 3) Familiarize yourself with how you use the product.
- 4) Replace the Handpieces compatible with the mirajet nozzles in the other laser surgery machine.
- 5) After fitting the handpiece, turn ON the other laser device body and prepare it for operation.

3.1.2 How to use and operation sequence

- 1) Open the package after checking the packaged direct injection device and the syringe injected with the chemical solution. (The syringe is on the market and uses a capacity of 1ml to 3ml.)



< Packaged Needle-free injector and a liquid-infused thread syringe >

- 2) Connecting the syringe injected with the medicine solution to the direct injection device



<syringe combined with injector >

NOTE : When connecting the syringe and the injection device, make sure that no air enters the inside as much as possible..

- 3) Move the nozzle upwards and slowly push the syringe handle until the drug is visible in the nozzle.
Fill the drug.



< Nozzle Photo >

NOTE : The chemical volume in the chamber is about 0.253 ml

- 4) Lightly beat the injector 20 times to allow the drug to be filled inside the nozzle.



NOTE: After tapping lightly, when you push the mill, the air bubbles come out "3times and 4times"
Repeat the process two or three times to pullout air bubbles inside the nozzle.

3.2 Recommend

Head screw assembly with handpiece M20 * P1.5

3.2 Connector

3.2.1 Connector connection

- 1) Check laser device body is turned off.
- 2) Connect the connector by hand to the articulated arm of the laser device body.



< Connect the connector to the articulated arm >

3.2.2 Needle-free injector connection

- 1) Connect the needle-free injection device to the connector.
- 2) Do not connect the sensing connector.



< Connect the Needle-free injector to the connector >

4. How to store and manage after use

- 1) Once opened, discard the product even if it is not used.
- 2) Do not reuse this product as it is a disposable product.

5. Precautions for use

5.1 General notes



- 1) This product is a disposable product and should be disposed of according to the designated method after use.
- 2) Once opened, discard the product even if it is not used.
- 3) It is prohibited to use sterilized products that have passed the expiration date or are opened or damaged individually.
- 4) Use other than general purpose is prohibited.
- 5) It is prohibited to reuse the chemicals inside the Needle-free injector, including syringes

5.2 Application notes



- 1) Do not use if foreign substance is found in the product before use.
- 2) It must be opened just before use to prevent secondary pollution.
- 3) When using this product, check the capacity of injectable and syringe of medicine to be used
- 4) When using, spraying by overlapping one part of skin may accumulate and cause side effects.
- 5) Prohibit reuse of leftover medicines

5.3 Side effect



- 1) When using the product, be careful not to infect the skin injection site or expose it to the blood...
- 2) excessive pain at the injection site. Pain, swelling, abnormal skin sensations and infections may occur.

5.4 Warning



- 1) This product is for single-use medical device. Do not reuse it after resterilizing.
- 2) Be careful not to spray directly into eyes when using.
- 3) When connecting the connector, check the manufacturer's specifications.

5.5. Sterilization method

STERILE**R**

Gamma sterilisation, ,

6. Expiration date

One year from the date of manufacture

7. How to save

Store in a cool place and avoid direct sunlight. Especially avoid high temperature and humid places.

8. Disposal

It should be handled according to local laws and regulations.

9. Symbols

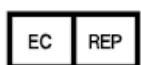
Symbol	Description
	Manufacturer
	Date of Manufacture
	Authorized representative in the European Community
	Batch code
	Serial number
	Use-by date
	Sterilized using irradiation
	Do not re-use
	Do not resterilize
	Consult instruction for use
	Do not use if package is damaged
	Humidity limitation
	Atmospheric pressure limitation
	Warning, Consult Accompanying Documents
	General mandatory action manual
	General prohibition indication

	KEEP AWAY FROM SUNLIGHT
	Handle with care
	This side up
	Keep Dry
	European Conformity mark CE Marking

10 User Manual Language :**1) Standard : English****2) Translation : Provides translations of manuals for each country's language****JSKBiomed Inc.**

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* This product is a medical device.