

REF P65-001-0001-SK

General Description

The Paragon FJ2000 range of disposable surgical power tools are designed for use in orthopedic osteotomies and a variety of precision small bone cutting and drilling procedures. The Paragon range is supplied in a sterile package "Ready to Use" and for Single-Use only.

The Handpiece with AO module attached offers a maximum speed of 10,000 rpm.



Read the operating instruction carefully before use. Failure to follow may cause damage or injuries.

Indications

Orthopedic osteotomies and a variety of precision small bone cutting and drilling procedures.

Contraindications

Must not be used for cranial surgery.

Warnings

Failure to follow may cause possible harm to persons.

- The device must be used solely by orthopedic surgeons and healthcare professionals trained to conduct orthopedic osteotomies and a variety of precision small bone cutting and drilling procedures.
- Wear protective equipment to avoid infectious splash backs.
- Sterile only if package is unopened and undamaged. Single use only! **DO NOT Re-sterilize!**
- **DO NOT** operate damaged or malfunctioning instruments.
- One P65-001-0001-SK device per operation.
- Federal law (USA) restricts this device to sale by or on the order of a physician or properly licensed practitioner.

Caution

Failure to follow may cause damage to product.

- **DO NOT** use this product in any other manner other than the purpose or the operation method described in this instruction manual.
- **DO NOT** submerge instrument in liquid.
- **DO NOT** drop or hit the instrument.
- Store in a cool dry place.
- No modification of this equipment is allowed.
- Personnel should familiarize themselves with the power equipment before it is set-up for use in any procedure. Trained personnel includes but is not limited to, central processing personnel, members of the surgical team, and the bioengineering department.
- Ensure the port switch is turned to the white port side

NOTE: The user/patient should report any serious incident relating to the device to the manufacturer and competent authority of its Member State.

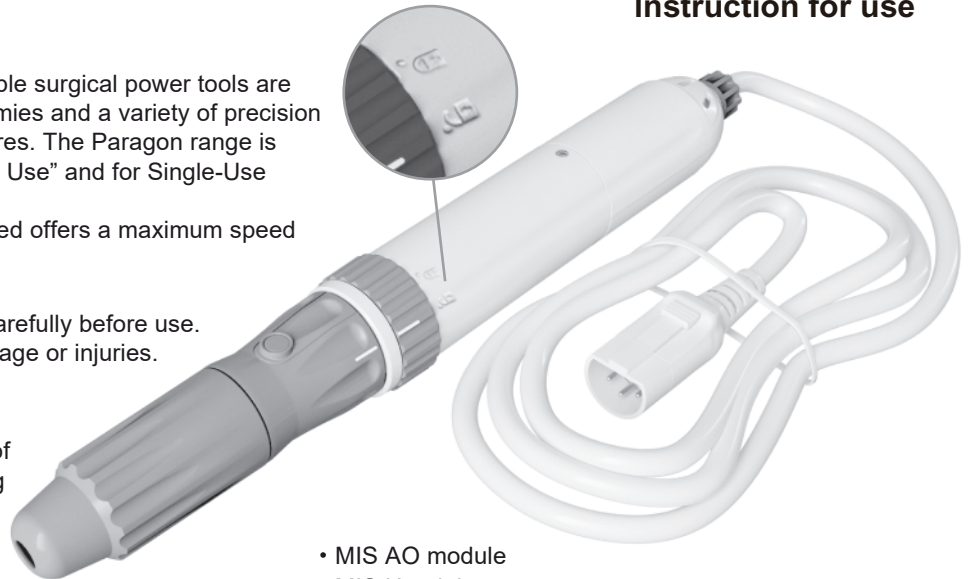
Instructions for Use

Plug into the Power Console Non-sterile Person:

Plug the handpiece white plug to the white port and make sure to turn the port switch to the white port side.



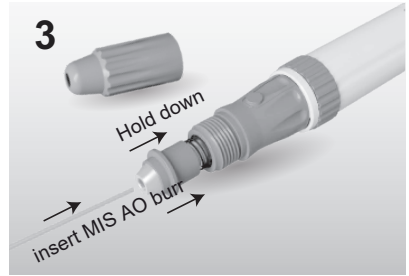
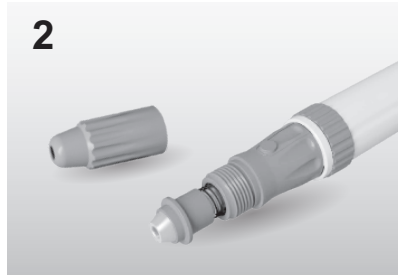
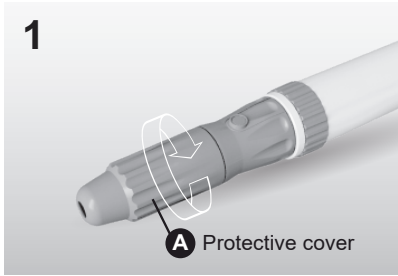
Instruction for use



- MIS AO module
- MIS Handpiece
- Burr NOT included

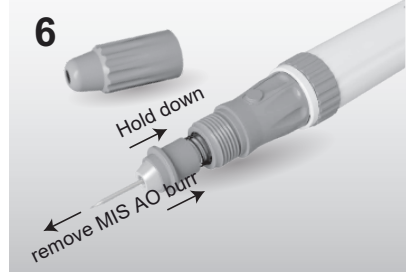
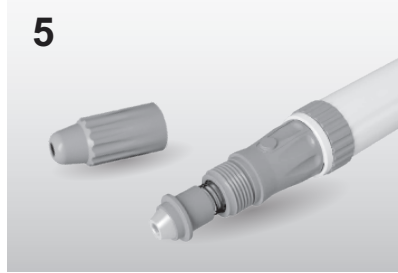
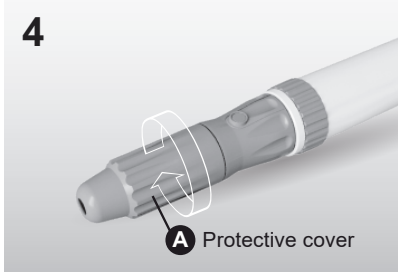
Installation **Sterile Person:**

Remove the protective cover **A**, then insert the MIS AO burr.

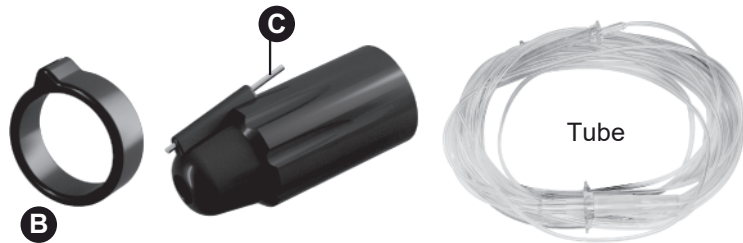


Removal **Sterile Person:**

Remove the protective cover **A**, then remove the drill bit.

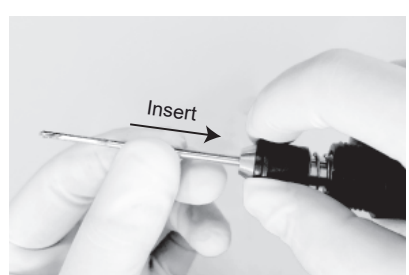


MIS Irrigation Kit (Optional)



Installation **Sterile Person:**

Insert the ring **B** on the handpiece and adjust the ring position. Then insert the MIS AO burr

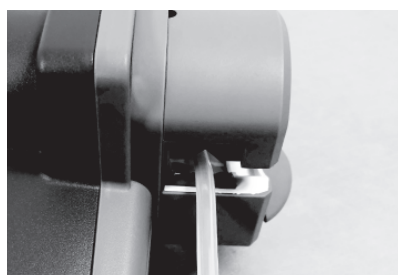


Install the protective cover, and connect the irrigation tube to the rod **C** and fix the tube on the ring **B**.

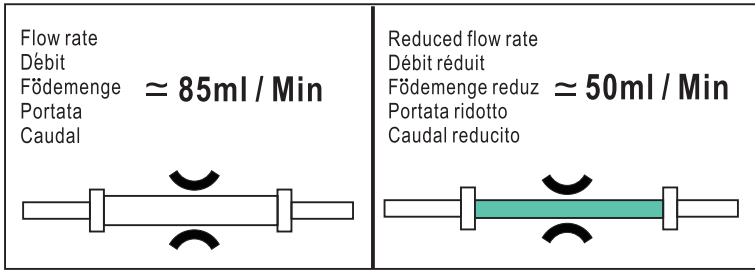


Non-sterile Person:

Open the pump by turning counter clockwise, make sure to insert the tube into the V aperture, and close the pump by turning clockwise.



NOTE: Irrigation flow differs according to which section of the tube is inserted to the pump.



Insert the spike into the irrigation solution.



Specifications

- Speed : 10,000 RPM (High)
8,000 RPM (Medium)
6,000 RPM (Low)
- Torque: 0.237 Nm (High)
0.189 Nm (Medium)
0.142 Nm (Low)
- AO bit module connector
- 24V DC Brushless Motor

Operation

- Temperature: 10°C~25°C
- Relative Humidity: 30%~75%RH
- Atmospheric Pressure: 80kPa ~106kPa
- Altitude limit: 2,000 meters

Transportation and Storage

- Temperature: -10°C~+40°C
- Relative Humidity: 15%~75%RH
- Atmospheric Pressure: 80kPa ~106kPa

Duty Cycle

Continuous operation with intermittent loading.
T_on:30s/ Min.T_off:30s for Max. 5 consecutive cycles

Shelf Life

3 years

Disposal

- Detach all power sources before disposal.
- Dispose of all single use components, as appropriate, immediately after use.
- Ensure that the device is disposed of safely and in accordance with all current national and international waste disposal directives. Please contact the local authorities responsible for waste disposal if questions arise.

Labeling Symbols

	Refer to instruction manual/booklet		Distributor		Use by date
	General warning sign / Caution		Importer		BF Type
	Do not reuse		Complies with EU directives		Date of manufacture
	Do not use if package is damaged		Manufacturer		Medical Device
	Keep Dry		Authorized representative in the European Community		Single sterile barrier system
	Sterilized using ethylene oxide		Swiss Authorised Representative		Single sterile barrier system with protective packaging outside
	Catalog number		UK Responsible Person		Single sterile barrier system with protective packaging outside, enclosed in a carton.
	Batch code				Humidity limitation
	Do not resterilize				Atmospheric pressure limitation
	Federal law (USA) restricts this device to sale by or on the order of a physician or properly licensed practitioner				Temperature limit

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