

REF P65-001-0011-SK

Instruction for use



Automatic K-wire module



Cannulated AO module



- MIS RS module
- MIS Handpiece

MIS RS burr, cannulated AO drill bit, and k-wire are NOT included

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 Minimally-invasive percutaneous procedures Kit comes with an MIS RS, K-wire, and Cannulated AO modules.



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

Indications

Orthopedic osteotomies, a variety of precision small bone cutting, drilling and k-wire placing procedure.

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.
- 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.

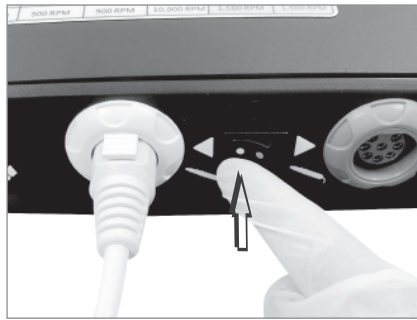
- **DO NOT** use this product in any other manner other than the purpose or the operation method described in this instruction manual.
- **DO NOT** submerge instrument in liquid.
- **DO NOT** drop or hit the instrument.
- Store in a cool dry place.
- No modification of this equipment is allowed.
- Personnel 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.

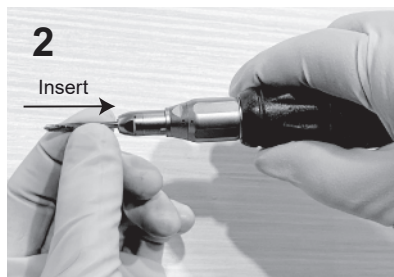
MIS RS module

Installation

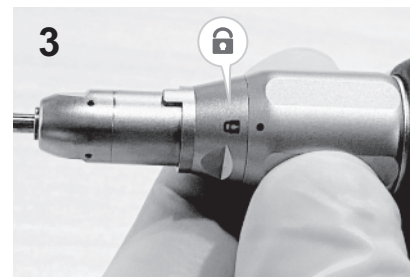
Sterile Person:



Turn to unlock the chuck mechanism



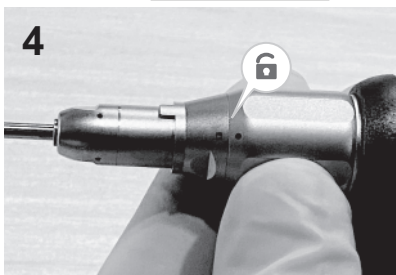
Insert the burr.



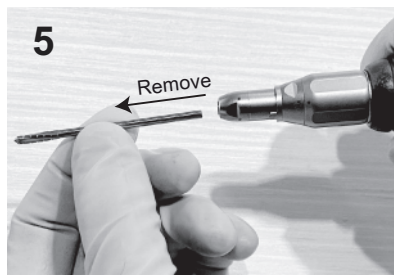
Turn to lock the chuck mechanism.

Removal

Sterile Person:



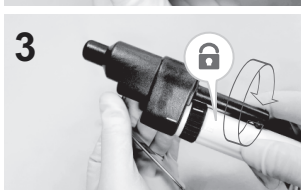
Turn to unlock the chuck mechanism.



Remove the burr.

Automatic K-wire module

Sterile Person:

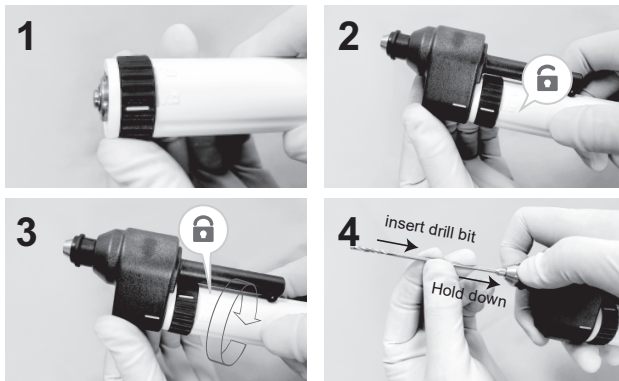


Assemble the Handpiece

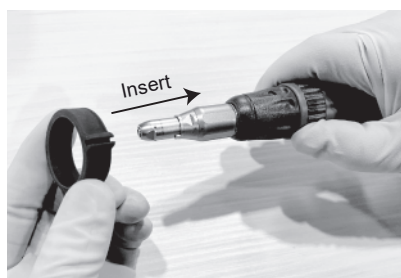
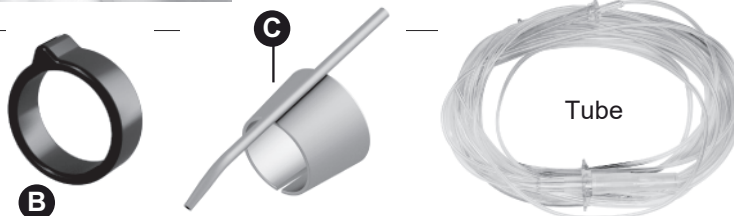
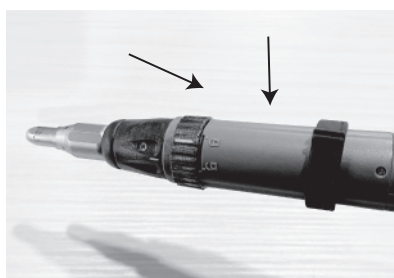
1. Ensure the twist lock on the handpiece is open (white line should be aligned with the opened lock symbol).
2. Attach the module to the handpiece by aligning both white lines.
3. Rotate the twist lock to lock the module in place (white line should be aligned with the closed lock symbol).

Insert the K-Wire

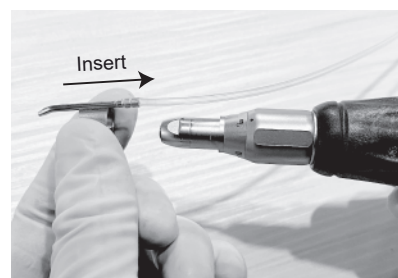
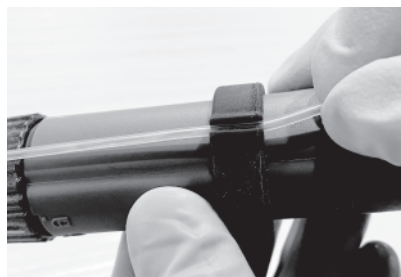
4. Insert K wires between 0.9 ~ 2.3 mm
5. Use the wire collet handle to hold the K-wire during use and placing.

Cannulated AO module**Sterile Person:****Assemble the Handpiece**

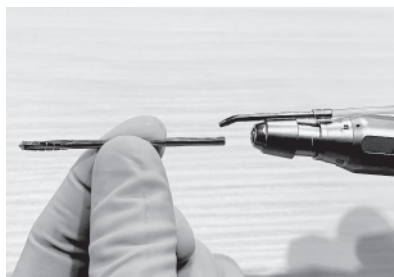
1. Ensure the twist lock on the handpiece is open (white line should be aligned with the opened lock symbol).
2. Attach the module to the handpiece by aligning both sides lines.
3. Rotate the twist lock to lock the module in place (white line should be aligned with the closed lock symbol).
4. Insert the cannulated/standard AO drill bit.

**P65-001-0008-SK
MIS Irrigation Kit RS
(Optional)**
Installation**Sterile Person:**Insert the ring. **B**

Adjust the ring position.

Insert the irrigation clip. **C**

Align the tube and fix it to the ring.



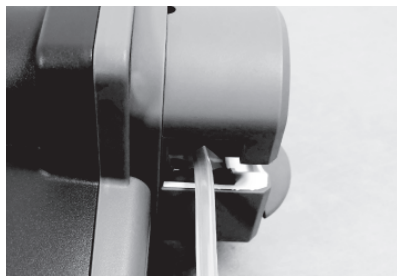
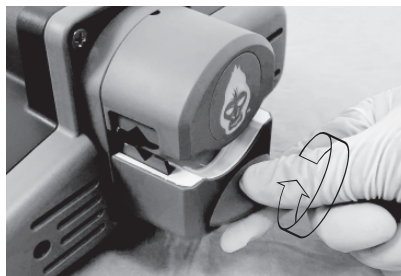
Turn to unlock the chuck mechanism and insert the burr.



Turn to lock the chuck mechanism.

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.

Flow rate Débit Födemege Portata Caudal	≈ 85ml / Min	Reduced flow rate Débit réduit Födemege reduz Portata ridotto Caudal reducido	≈ 50ml / Min

Insert the spike into the irrigation solution.



Specifications

- **MIS Handpiece**
24V DC Brushless Motor
- **MIS RS Module**
Round shank bit module connector
- **Cannulated AO Module**
AO bit module connector
- **Automatic K-Wire Module**
Diameter capacity: 0.9~2.3 mm

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

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.

Port in White			
	MIS Module	Automatic K-Wire	Cannulated AO
Speed and Torque			
HIGH	10,000 RPM	1,500 RPM	1,500 RPM
	0.237 Nm	1,577 Nm	1,577 Nm
MEDIUM	8,000 RPM	1,200 RPM	1,200 RPM
	0,189 Nm	1,261 Nm	1,261 Nm
LOW	6,000 RPM	900 RPM	900 RPM
	0,142 Nm	0,946 Nm	0,946 Nm

Duty Cycle

- **MIS RS Module**
Continuous operation with intermittent loading.
(max. 30 seconds ON then 30 seconds OFF for 5 consecutive cycles)
- **Automatic K-Wire Module**
Continuous operation with intermittent loading.
(max. 30 seconds ON then 10 seconds OFF for 20 consecutive cycles)
- **Cannulated AO Module**
Continuous operation with intermittent loading.
(30 seconds ON then 30 seconds OFF for 5 consecutive cycles)

Labeling Symbols



Refer to instruction manual/booklet



General warning sign / Caution



Do not reuse



Do not use if package is damaged



Keep Dry



Sterilized using ethylene oxide



Catalog number



Batch code



Do not resterilize



Distributor



Importer



Complies with EU directives



Manufacturer



Authorized representative in the European Community



Swiss Authorised Representative



UK Responsible Person



Unique Device Identifier



Use by date



BF Type



Date of manufacture



Medical Device



Single sterile barrier system



Single sterile barrier system with protective packaging outside



Single sterile barrier system with protective packaging outside, enclosed in a carton.



Humidity limitation



Atmospheric pressure limitation



Temperature limit

R Only Federal law (USA) restricts this device to sale by or on the order of a physician or properly licensed practitioner



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